Document III-A: Study Summaries - Active Substance Boric Acid

Section A1

Annex Point IIA1 Applicant 1.1 Applicant Lea

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Joint Notifier Etimine s.a.
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Administrative Consortium Lead
Dr Roger Doome
c/o European Borates Association (EBA)
[redacted]
Email: [redacted] r.doome@ima-europe.eu

Official use only

1.2 Manufacturer of Active Substance **(if different)** **Borax Europe Ltd**
Borates for Biocidal use are manufactured in the USA
US Borax Inc
14486 Borax Road
Boron, CA 93516-2000
USA
Tel: + 1 760 762 7000

Etimine s.a.
Borates for Biocidal use are manufactured in Turkey
Eti Mine Works
Cihan Sk No: 2
06100 Sihhiye
Ankara
Turkey

X1

1.3 Manufacturer of Product(s) (if different)

As above

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and Methods	Section 1.2 Manufacturer The notifier noted that there are two locations for production of the active substance by Etimine S.A.: 1) Eti maden isletmeleri g.m. Bandirma bor ve asit fab. Islt. Müdürlügü 10200 Bandirma/Balikesir Turkey Tel: +90 (266) 7213100 Fax: +90 (266) 7213126 2) Eti maden isletmeleri g.m. Emet kolemanit Islt. Müdürlügü 43700 Emet/Kütahya Turkey Tel: +90 (274) 4613400 Fax: +90 (274) 4613403 The address of Borax Europe Ltd. is correct.
Conclusion	-
Reliability	-
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document III-A: Study Summaries - Active Substance Boric Acid

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	Boric acid ortho boric acid, boracic acid and boric acid; Borax Europe Trade name: Optibor	X1
2.2	**Chemical name (IIA2.2)**	ortho-boric acid	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable	
2.4	**CAS No and EC numbers (IIA2.4)**	Non-entry field	X2
2.4.1	**CAS-No**	10043-35-3	
2.4.2	**EC-No**	233-139-2	
2.4.3	**Other**	Not relevant	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**	Non-entry field	
2.5.1	**Molecular formula**	H_3BO_3	X3
2.5.2	**Structural formula**	Boric acid consists of H-bonded trigonal B(OH)3 molecules arranged in layers. See structure attached to IUCLID database	X4
2.5.3	**Molecular mass**	61.8	X5
2.6	**Method of manufacture of the active substance (IIA2.1)**	[redacted]	X6

Section A2 [redacted]

[redacted]

See also section 2.10.1.1

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

g/kg g/l % w/w % v/v

X7

Borax Europe Ltd:

Optibor TG	% w/w	
	B2O3	Purity
Typical	56.38	100.13
Maximum	56.80	100.9
Minimum	56.25	99.9

Etimine s.a.:

	% w/w	
Boric Acid	B2O3	Purity
Typical	56.36	100.12
Maximum	56.49	100.34
Minimum	56.30	100.00

The possibility in the purity being ≥ 100% is due to the variation of crystal water in boric acid. Since boric acid consists of diboron-trioxide and water ($H_3BO_3 \leftrightarrow 1/2B_2O_3 + 3/2H_2O$), even a slight decrease in the structural water content will yield to a higher diboron-trioxide content which will increase the purity

2.9 The origin of the natural active substance or the

X8

Natural inorganic mineral ore

Borax Europe Limited: Ores

Section A2 Identity of Active Substance

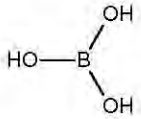
precursor(s) of the active substance (IIA2.9)	Tincal ($Na_2O.2B_2O_3.10H_2O$) *Kernite ($Na_2O.2B_2O_3.4H_2O$)* Etimine data to be submitted via EBA

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-Feb-05
Materials and Methods	Section 2.1, Common name a. Common name should be discerned from synonyms and trade names. b. More synonyms were found in the IUCLID database for existing substances: acidicum boricum, boron trihydroxide, trihydroxyborane.
Conclusion	Common name: boric acid Synonyms: orthoboric acid, boracic acid, acidicum boricum, boron trihydroxide, trihydroxyborane
Reliability	-
Acceptability	acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and Methods	Section 2.4 CAS number and EC number. In the 29th ATP, 27th May 2003 two entries were given: * Boric acid, CASno 10043-35-3, EC no 233-139-2. * Boric acid, crude natural, containing not more than 85% of H_3BO_3 calculated on the dry weight CAS no 11113-50-1 and EC no 234-343-4. These entries correspond with the RAR for boric acid and disodium tetraborate (17 December 2003, document TR417+423_1203_env_hh).
Conclusion	Two CAS numbers exist for the same compound. * Boric acid, CASno 10043-35-3 * Boric acid, crude natural, containing not more than 85% of H_3BO_3 calculated on the dry weight, CAS no 11113-50-1. For this CA-report, CAS no is 10043-35-3 is used (pure boric acid). CAS no 11113-50-1 is only used for natural boric acid and is not assessed in this CA-report. Two EC numbers exist for the same compound. * Boric acid, EC no 233-139-2. * Boric acid, crude natural, containing not more than 85% of H_3BO_3 calculated on the dry weight, EC no 234-343-4. For this CA-report, EC no is 233-139-2 is used (pure boric acid). EC no 234-343-4 is only used for natural boric acid and is not assessed in this CA-report.
Reliability	-
Acceptability	acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1-Feb-05
Materials and Methods	Section 2.5.1: Molecular formula. Although the general formula is H_3BO_3, other frequently used formulas are: $B(OH)_3$ or $B_2O_3.3H_2O$ References: * Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 372. Published. * Bell RP, Edwards JO and Jones RB (1967) The structure and acidity of boric acid and their relation to reaction mechanisms. *In*: The chemistry of boron and its compounds. pp 209-221. Published. Submitted for IIIA3.6.
Conclusion	General formula H_3BO_3. Other frequently used formulas are: $B(OH)_3$ or $B_2O_3.3H_2O$
Reliability	-
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21-Feb-05
Materials and Methods	Section 2.5.2: Structural formula The notifier refers to the IUCLID database for the structural formula. The structural formula should also be given here.
Conclusion	Structural formula: 
Reliability	-
Acceptability	acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and Methods	Section 2.5.3, Molecular mass a. It is not clear where the molecular mass as submitted by the notifier came from. The molecular mass is given as 61.833 in the CRC Handbook of Chemistry and Physics, version 1999. This molecular mass is used throughout the CA-report. b. Because several molecular formulas exist for the same compound, the molecular formula should be specified
Conclusion	molecular mass is 61.833 for H_3BO_3
Reliability	-
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1-Feb-05
Materials and Methods	Section 2.6: Manufacturing process a. The manufacturing process for Borax Europe Limited is considered as an industrial scale process, although this is not indicated by the notifier. b. The manufacturing process of Etimine s.a. is classified as confidential. The description of the process is given in a separate appendix, indicated as Doc IIIA (2.6 and 2.9) Etimine. Please note that 110 °F = 43.3 °C
Conclusion	as indicated by the notifier
Reliability	-
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and Methods	Section 2.7: Purity of the active substance a. The specification data cannot be verified by the RMS, because batch analyses are not submitted. These are however not required. b. A boric acid purity higher than 100% is not possible. c. Another frequently used formula for boric acid is $B_2O_3.3H_2O$. Based on this formula the purity can also be expressed as B_2O_3-content. In this case 56-57% B_2O_3. It is not useful to express the content as boric oxide, because this compound as such is not present in boric acid. The formula suggests that boric acid is boric oxide with added crystallisation water, which is not correct. Both boric oxide and water are not present in boric acid. d. The minimum purity data for the Etimine s.a. product (100%) do not comply with impurity data (see IIIA2.8). Based on impurity data (see IIIA2.8) a minimum purity of 99.9% (w/w) is possible for both manufacturers. e. The minimum purity data for both manufacturers (99.9% or 100%) do not comply with the purity of the active substance used in tests for physical chemical properties (see IIIA3.1.1; IIIA3.1.3; IIIA3.4, IIIA3.5, IIIA3.9). In these tests the minimum purity was 99.0%. f. The minimum purity data for the Etimine s.a. product (100%) do not comply with the purity of the active substance used in a test for vapour pressure (see IIIA3.2). In this test the minimum purity was 99.9%.
Conclusion	Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) expressed as H_3BO_3 for both manufacturers.
Reliability	-
Acceptability	acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1-Feb-05
Materials and Methods	Section 2.9: Origin of natural active substance The origin of the natural active substance of Etimine s.a. is classified as confidential. The origin is given in a separate appendix, indicated as Doc IIIA (2.6 and 2.9) Etimine.
Conclusion	as indicated by the notifier
Reliability	-
Acceptability	acceptable.
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document III-A: Study Summaries - Active Substance Boric Acid

Section A2 Identity of Active Substance

Subsection (Annex Point)		Official use only
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	X1

Borax Europe Ltd.:

Major impurities measured in Boric acid (manufactured in the USA by US Borax and sold by Borax Europe):

Optibor TG	% w/w		
	Fe	Cl	SO_4
Typical	0.0002	0.0004	0.0211
Maximum	0.0006	0.0018	0.0350
Minimum	0.0000	0.0000	0.0000

Variation in the purity and impurities is also due to the degree of hydration of boric acid. This variable is dependant on the manufacturing process (see Document IIIA Section 2.6, Manufacturing Process: Drying stage). Therefore water will be the difference up to 100%.

Etimine s.a.

Boric Acid	%			
	Fe	Cl	SO_4	Insolubles in water
Typical	0.0004	0.0007	0.0104	0.0087
Maximum	0.0009	0.0014	0.0130	0.0100
Minimum	0.0002	0.0003	0.0063	0.0060

Insolubles in water consist of Ca, Mg, Si, Al etc.

2.8.1 Isomeric composition

Not relevant

RMS, Section A2.8

Annex Point IIA2.8

Identity of impurities and additives (active substance)

fill in one form for each impurity/additive

RMS 2.8.1 Common name and function

non-entry field

RMS 2.8.1.1. Common name

traces of iron, chlorine, sulphate

RMS 2.8.1.1. Function

impurity of starting material

RMS 2.8.2 IUPAC name

not applicable

RMS 2.8.3 CAS no

not applicable

RMS 2.8.4 EC no

not applicable

RMS 2.8.5 Other

not applicable

RMS 2.8.6 Molecular formula

Fe, Cl, SO_4

RMS 2.8.7 Structural formula

unknown

RMS 2.8.8 Molecular mass

Fe = 55.845
Cl = 35.4527
SO_4 = 32.066(6) + 4x 15.9994(3) = 96.043
Reference:
CRC Handbook of Chemistry and Physics, 1999

RMS 2.8.9 Concentration of impurity or additive
typical and range of concentrations

Borax Europe Ltd.:

Major impurities measured in Boric acid (manufactured in the USA by US Borax and sold by Borax Europe):

Optibor TG	% w/w		
	Fe	Cl	SO_4
Typical	0.0002	0.0004	0.0211
Maximum	0.0006	0.0018	0.0350
Minimum	0.0000	0.0000	0.0000

Variation in the purity and impurities is also due to the degree of hydration of boric acid. This variable is dependant on the manufacturing process (see Document IIIA Section 2.6, Manufacturing Process: Drying stage). Therefore water will be the difference up to 100%.

Etimine s.a.

Boric Acid	%			
	Fe	Cl	SO_4	Insolubles in water
Typical	0.0004	0.0007	0.0104	0.0087
Maximum	0.0009	0.0014	0.0130	0.0100
Minimum	0.0002	0.0003	0.0063	0.0060

Insolubles in water consist of Ca, Mg, Si, Al etc.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 2.8 Identity of impurities a. The summary written by the notifier is not according to the template. Therefore the whole section was rewritten by the RMS. b. The specification data for impurities cannot be verified by the RMS, because batch analyses were not submitted. These are, however, not required. c. The impurities for the Borax Europe Ltd and Etimine s.a. product add up to a maximum of 0.0374% and 0.025%, respectively, assuming that the concentrations are stated as % w/w. For the Etimine s.a. product, this is higher than can be expected from the minimum purity requirement for the active substance of 100.00% w/w (see section IIIA2.7) as indicated by the notifier. But the impurities for both manufacturers are compliable with the proposed minimum purity of 99.0% as proposed by the RMS (see section IIIA2.7).
Conclusion	Maximum specified impurities are compliable with the minimum purity of 99.0% (w/w) expressed as H_3BO_3 as proposed by the RMS for both manufacturers.
Reliability	-
Acceptability	acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document III-A: Study Summaries - Active Substance Boric Acid

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

Subsection		Official use only
2.10.1 Human exposure towards active substance	In the occupational exposure measurements of borates it is preferential to determine the boron value of the sample and to equate this to individual borates where appropriate. The basis for this is due to a number of factors. 1. Borates are susceptible to weight change due to uptake or loss of water and this hydration instability can lead to gravimetric and interpretation errors in field samples. 2. There may be a mix of borates in the sample and borate species can not be easily characterised by chemical analysis. 3. Boron can be measured to a high level of accuracy. REF: Smith, R.A.; Ascherl, F.M Issues concerning the measurement of borate in occupational environments. Am. Ind. Hyg. Assoc. J., 60, No. 5, p.651-658. (September - October 1999)	
2.10.1.1 Production		
i) Description of process	The Active ingredients are manufactured outside the EU and are imported in to Europe in big bags and bulk by ship or road tanker for packaged products (~1.0 tonnes). The principle processes in Europe are: bulk unloading of ships using bucket grabs for bulk into hoppers and conveyed to bulk storage silos, shore cranes for packaged products, transfer of product from big bags into road tanker using closed screw conveyor, blowing product from road tanker into silos using compressors, transfer of product within the facilities is carried out using closed screw conveyor belts or enclosed pneumatic systems. Product is distributed to customers from the operations through bulk loading of rail cars, trucks and barges - using closed screw conveyors and gravity feed. Products are also packaged in IBCs varying from 25 kilo bags, 500 kg to 1.2 tonnes and.	
ii) Workplace description	Work place conditions relate to the moving, handling and packaging of borates in powdered form. Handling of product ranges from non-dispersive/ with no direct handling (bulk unloading) to wide dispersive use with direct handling (maintenance and cleaning). Bag filters are fitted at all filling and transload points – hoppers, silos, tanker filling and discharge points and bagging stations. Most of the transport of product uses a completely enclosed pneumatic transport system. Some bagging operations operate on a completely closed system. Where airborne dust exceeds the legal limit appropriate Dust masks are provided. In addition gloves, eye protection and hard hats are worn where appropriate.	
iii) Inhalation exposure	The primary route of exposure to the active ingredient is through inhalation of dust. Unloading of ships takes place for approximately 30 days a year. Bagging of product is intermittent but carried out on 200 days of the year. The frequency of exposure for maintenance workers is one of the highest Measured occupational exposures range from 0.01 – 6.9 mg B/m^3. With the exception of front end loading activities and sweeping activities during the unloading of the vessel, measured. The average mean exposures are around 0.5 mg B/m^3 or less.	
iv) Dermal exposure	Dermal exposures are extremely low since borates are not absorbed across intact skin.	

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

2.10.1.2 Intended use(s)

As discussed in Doc IIIB, evaluate the safety of the use of borates one model Biocidal Product will be assessed as a representative of the highest exposure and the following assumption made

1. The product is formulated from any one of the boric acid; boric oxide; disodium tetraborate (wither anhydrous, pentahydrate or decahydrate) and disodium octaborate tetrahydrate to give the relevant equivalent boric acid level
2. It is used as a aqueous solution
3. For industrial use the operators buy borates either in bulk, in IBCs or 25 kg bags and mix at the necessary quantities in a closed system to the level in boric acid equivalents that is needed to obtain the loading in the wood to comply with EU Standards.
4. For professional use, borates can be purchased in 25 kg bags for mixing on site to the specified use conditions. A formulator will also buy the separate products to construct his own formulation.
5. For Amateur users it will be assumed that Ready for Use formulations will be available
6. A Risk Assessment of the Mixing and Loading using the different borates will be presented

Mixing and Loading Exposure Estimates Industrial and Professional Users

The following conservative assumption were made as a worst case scenario (See more detail in Exposure Assumptions for All Users below)

- Whole Body Exposure
- PPE for industrial users; 10% Protection
- With and without hand protection. PPE estimated to provide only 50% protection without hand protection
- Body Weight 70 kg
- Exposure time 1.5 hours per day

Parameter	Boric Acid	Disodium Octaborate Tetrahydrate	Sodium Tetraborate Decahydrate	Sodium Tetraborate Pentahydrate
Body Surface Area	19400	19400	19400	19400
Exposure Time	1.5	1.5	1.5	1.5
Boron Dermal Absorption Flux ($\mu g.cm^2$ /hour)	0.00158	0.0021	0.00102	0.00134
PPE Factor	0.1	0.1	0.1	0.1
Body Weight	70	70	70	70
Dose	**6.6E-05**	**8.7E-05**	**4.2E-05**	**5.6E-05**
Dose Assuming no hand protection*	**3.3E-04**	**4.4E-04**	**2.1E-04**	**2.8E-04**

* This assumes 0.5% protection from general clothing worn

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

Exposure Estimates from Use

1. Industrial Users

Each scenario includes a mixing and loading task in which bags or bins of product in powder form are moved, opened, poured into a mixing vessel, and diluted by the industrial worker receptor.

VACUUM AND DOUBLE VACUUM PRESSURE IMPREGNATION

The product is applied to the wood in purpose-built industrial timber treatment plants where the timber is treated under vacuum and pressure conditions in a closed vacuum pressure timber treatment vessel using penetrating treatment processes. The process conditions are selected according to the timber species being treated and the use class in which the treated timber will be placed. The product may be applied to green (unseasoned) or to dry (seasoned) timber.

The product is supplied as a powder, which is mixed with clean water in the concentrate storage, product mixing and dilution system. The solution strength of the ready-to-use treatment solution is varied according to the wood preservative specification required for the end use application of the treated timber. The wood preservative is typically delivered in bags or "bulk bins" and stored at the treatment plant site. The product is poured into a mixing tank and mixed with water to produce the ready-to-use timber treatment solution. Apart from opening the bags the product mixing is done within closed pipe work with little or no risk of exposure to the operating personnel. No additional substances are added to the product.

A number of timber treatment processes (or cycles) are used in industrial wood preservation, all of which involve the use of varying vacuum and pressure periods and intensities. The processes involved in treating dry timber are (1) application of an initial vacuum, (2) the vessel (a cylinder or autoclave) is filled with ready-to-use preservative solution and pressure, usually hydraulic, is applied to force the preservative deeper into the wood, (3) the vessel is emptied of preservative solution and a final vacuum is used to recover a proportion of the wood preservative (for re-use), (4) the storage tank containing the ready-to-use solution is then topped-up by mixing concentrate with water. This is done internally within the plant pipe work.

The process is closed. The only processing waste generated is sludge produced from sawdust or dirt brought into the vessel on the wood to be treated. After treatment the freshly treated timber is held at the timber treatment plant for post-treatment conditioning to take place.

Typically, one person operates timber treatment plants, although companies will have several personnel qualified to operate the plant to ensure continuity of treatment production. Some plant locations have more than one timber treatment plant.

The following table identifies the scenario, task code (as defined in Section 3.2, Part 2, of *Technical Notes for Guidance* [DGE, 2002]), the exposure time per cycle and the controls that are in place at the timber treatment plant.

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

Scenario	Task Code	Time per treatment cycle	Potential Exposure routes and controls
Mixing and Loading phase			
Handling wet objects	1.1.3	5 min	**Dermal: Hands- protective gloves, coverall**
Emptying bags containing product into mixing vessel	1.1.4	5 min	**Inhalation: dust masks/LEV** Dermal: Hands- protective gloves, coveralls
Dilute product in plant	1.5.2	5 min	**None as dilution done inside plant pipe work**
Application phase			
Treatment vessel			
Load wood onto carrier (bogie) done mechanically	1.1.4	5 min	**Dermal- gloves, coverall**
Secure with restraining straps	1.1.3	5 min	**Dermal – gloves, coverall**
Push carrier into vessel by mechanical means	1.1.3	1 min	**Potential for dermal pick-up from contaminated controls**
Seal door, operate process	1.4.4	2 min	**Potential for dermal pick-up from contaminated controls**
Open door at the end of the cycle	1.1.3	1 min	**Potential for dermal pick-up from contaminated controls; inhalation of aerosol on opening door**
Remove carrier (bogie) from vessel by mechanical means	1.1.4	5 min	**Potential for dermal pick-up from contaminated controls**
Release restraining straps	1.1.3	2 min	**Dermal- gloves, coverall**
Convey treated wood to holding area, by lift truck	1.1.3	5 min	**Gloves off to drive lift truck, Potential for dermal pick-up from contaminated controls**
Post-application phase (includes disposal)			
Treatment vessels			
Grease / replace door seals and other maintenance tasks	1.6.1	5 min- 60 min	**Hands – gloves, coverall**
Remove fallen wood from vessel	1.6.1	5 min	**Dermal- gloves, coverall**
Clear sump / sludge	1.6.1	Up to 60 min	**Dermal: gloves, coveralls, protective footwear, eye protection**
Sampling of treating solution	1.6.2	5 min	**Dermal: Hands- none**
Disposal – tanker, disposal of bags	1.1.3/ 1.5.2	Up to 60 min	**Dermal: Hands- protective gloves**

These activities (i.e. task no.1.6.1 and disposal) do not occur every day. The mixing and loading activities comprise an estimated 15 minutes per cycle, while the application activities comprise 26 minutes per cycle. Assuming five cycles daily (DGE, 2002), this is a total of 75 minutes for mixing and loading and 130 minutes for application. The intermittent post-application processes can range from 15 minutes to 3.25 hours.

For quantitative purposes, 1.5 hours spent daily in mixing and loading activities, and 3 hours for application was assumed. These are overestimates, and are designed to adequately incorporate the additional exposures from sporadic post-application and disposal activities.

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

INDUSTRIAL DIPPING APPLICATION

The product is applied to the wood in purpose-built industrial dipping tanks where the timber is immersed in the ready-to-use treating solution. The process conditions are selected according to the timber species being treated and the use class in which the treated timber will be placed. The product is applied to green (unseasoned) wood and there is a post-treatment diffusion period.

The wood preservative solution is typically delivered in bags or "bulk bins" and stored at the timber treatment plant. The product is supplied to the facility as a water-soluble powder that is mixed with clean water in the product mixing and dilution system. This step is conducted within closed pipe work, with little or no risk of exposure to the operating personnel. There are no additional substances added to the product. The solution strength of the ready to use treatment solution is varied according to the thickness of the timber to be treated and to achieve the required cross-sectional, core and sapwood product retention.

The prepared solution is held in a large, open tank, which may or may not be located under cover. Bundles or packs of timber are mechanically lifted onto horizontal arms situated on a masthead. These are then mechanically lowered and submerged into the tank. Restraining bars prevent the timber from floating. To ensure that all faces of the timber are completely wetted and uniformly treated the timber is raised and lowered into and out of the treating solution two or three times. The time duration of each immersion is usually about 1 to 2 minutes. After the final immersion the timber is held above the tank to allow excess liquid to fall into the tank. Runoff from the timber into the tank can be promoted by holding the packs on a slight slope. After dripping the timber is then mechanically moved to a post-treatment holding area where it is covered or held in retarded drying conditions for the required diffusion period.

Typically, dipping plants are operated by one or two persons, although companies will have several personnel qualified to operate the plant to ensure continuity of treatment production. Some plant locations have more than one dipping plant.

The following table identifies the scenario, task code (as defined in DGE, 2002), the exposure time per cycle and the controls that are in place at the dipping plant. The temperature is typically 40 –60°C.

Scenario	Task Code	Time per treatment	Potential Exposure routes and controls
Mixing and Loading phase			
Handling wet objects	1.1.3	5 min	**Dermal: Hands- protective gloves, coverall**
Emptying bags containing product into mixing vessel	1.1.4	5 min	**Inhalation: dust masks** Dermal: Hands- protective gloves
Dilute product in plant	1.5.2	5 min	**None as dilution done inside plant pipe work**
Application phase			
Dipping Tank			
Load wood onto carrier arms (bogie) done mechanically	1.1.4	5 min	**Dermal- gloves, coverall**

Load wood onto carrier arms (bogie) done mechanically	1.1.4	5 min	Dermal- gloves, coverall
Secure with restraining straps, may be done by restraining arms	1.1.3	5 min	Dermal – gloves, coverall
Mechanically lower the timber into the treatment liquid	1.1.3	1 min	Potential for dermal pick-up from contaminated controls
Repeated raising and lowering of the timber	1.4.4	5 min	Potential for dermal pick-up from contaminated controls
Final raising from liquid	1.1.3	1 min	Potential for dermal pick-up from contaminated controls;
Allowing the timber to drain and drip	1.1.3	30+ min	Potential for dermal pick-up from contaminated controls
Release restraining straps	1.1.3	2 min	Dermal- gloves, coverall
Convey treated wood to holding area, by lift truck	1.1.3	5 min	Gloves off to drive lift truck, Potential for dermal pick-up from contaminated controls
Post-application phase (includes disposal)			
Covering the timber with tarpaulin already contaminated with product	1.1.3	30 min	Dermal-Hands – gloves and coverall
Grease / and other maintenance tasks	1.6.1	5 min- 60 min	Hands – gloves, coverall
Remove fallen wood from vessel	1.6.1	5 min	Dermal- gloves, coverall
Clear sump / sludge	1.6.1	Up to 60 min	Dermal: gloves, coveralls, protective footwear, eye protection
Sampling of treating solution	1.6.2	5 min	Dermal: Hands- none
Disposal – tanker, disposal of bags	1.1.3/ 1.5.2	Up to 60 min	Dermal: Hands- protective gloves

These activities (i.e., 1.6.1 and following) do not occur every day. The mixing and loading activities comprise an estimated 15 minutes per cycle, while the application activities comprise 24 to 54 minutes per cycle. The majority of the 30 minutes duration for the drain and drip activity will not involve direct human interaction. Therefore, actual exposure time for this activity was assumed to be 5 minutes (combining exposure at the beginning and end of the time period). Incorporating this assumption leads to an estimate of 29 minutes per cycle.

Assuming five cycles daily (DGE, 2002), this is a total of 75 minutes for mixing and loading and 145 minutes for application.

The intermittent post-application processes can range from 45 minutes to 220 minutes (or 3.7 hours). For quantitative purposes, 1.5 hours spent daily in mixing and loading activities, and 4 hours for application was assumed These are overestimates, and are designed to adequately incorporate the additional exposures from sporadic post-application and disposal activities.

INDUSTRIAL SPRAY TUNNEL APPLICATION

The product is applied to the wood in purpose-built industrial spray tunnels where the timber is coated by coarse spray nozzles. The product is applied to green (unseasoned) wood and there is a post-treatment diffusion period.

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

The wood preservative solution is typically delivered in bags or bulk bins and stored at the timber treatment plant. The product is supplied as a water-soluble powder that is mixed with clean water in the product mixing and dilution system. This is done within closed pipe work with little or no risk of exposure to the operating personnel. The solution strength of the ready to use treatment solution is varied according to the thickness of the timber to be treated and to achieve the required cross-sectional, core and sapwood product retention. There are no additional substances added to the product.

Individual boards are either mechanically or hand fed through the spray tunnel and then stacked for the diffusion process either under cover or in retarded drying conditions. Very thick boards (75-126 mm) require a second application of product.

The following table identifies the scenario, task code (as defined in DGE, 2002), the exposure time per cycle and the controls that are in place at the dipping plant. The temperature is typically 40 –60°C.

	Task	Time per	Potential Exposure
Mixing and Loading phase			
Handling wet objects	1.1.3	5 min	**Dermal: Hands-**
Emptying bags containing	1.1.4	5 min	**Inhalation: dust masks**
Dilute product in plant	1.5.2	5 min	**None as dilution done**
Application phase			
Handling the treated timber,	1.1.3	Period of	**Dermal – gloves,**
Convey treated wood to	1.1.3	5 min	**Gloves off to drive lift**
Post-application phase (includes disposal)			

Post-application phase (includes disposal)			
Covering the timber with tarpaulin already contaminated with product	1.1.3	30 min	**Dermal-Hands – gloves and coverall**
Cleaning nozzles	1.6.1	30 min	**Dermal- hands probably not wearing gloves.**
Grease / and other maintenance tasks	1.6.1	5 min- 60 min	**Hands – gloves, coverall**
Remove fallen wood from vessel	1.6.1	5 min	**Dermal- gloves, coverall**
Clear sump / sludge	1.6.1	Up to 60 min	**Dermal: gloves, coveralls, protective footwear, eye protection**
Sampling of treating solution	1.6.2	5 min	**Dermal: Hands- none**
Disposal – tanker, disposal of bags	1.1.3/ 1.5.2	Up to 60 min	**Dermal: Hands- protective gloves**

It should be noted that these activities i.e. 1.6.1 and disposal do not occur every day. The mixing and loading activities comprise an estimated 15 minutes per cycle, while the application activities can range from 5 minutes per cycle to an entire workday. However, it is not feasible to expect that a worker would be in direct contact with treated wood during the application phase for an entire workday. Therefore, actual exposure time for the application phase was assumed to be 4 hours, or one-half a workday. This limits the number of potential cycles for mixing and loading to 2 per day. For quantitative purposes, it was assumed that 0.5 hours spent daily in mixing and loading activities, and 4 hours for application. The intermittent post-application processes can range from 75 minutes to 250 minutes (or 4.2 hours). For quantitative purposes, 2 hours daily to cover these sporadic activities was added. Therefore, an exposure time of 6 hours daily for the application and post application phases has been used.

INDUSTRIAL DELUGE/FLOOD APPLICATION

The product is applied to the wood (which may be in the form of fabricated panels) in purpose-built industrial deluging chambers where the timber is coated with the treating solution applied through coarse spray nozzles or a curtain of liquid. The process is primarily applied to green wood.

The wood preservative is typically delivered in bags or bulk bins and stored at the application site. The product is supplied as a water-soluble powder that is mixed with clean water in the mixing and dilution system. There are no additional substances added to the product. This type of application may include the use of pigments and dyes to colour the timber substrate.

The solution strength of the ready to use treatment solution is varied according to the thickness of the timber to be treated and to achieve the required cross-sectional, core and sapwood product retention.

Individual panels are either mechanically or hand fed through the deluging curtain of liquid and then stacked for the diffusion process either under cover or in retarded drying conditions. The excess liquid is collected at the bottom of the deluge system and recycled by pumping it round the pipe work again.

The following table identifies the scenario, task code (as defined in DGE, 2002), the exposure time per cycle and the controls that are in place at the deluging plant. The temperature is typically 40 –60°C.

Scenario	Task Code	Time per treatment	Potential Exposure routes and controls
Mixing and Loading phase			
Handling wet objects	1.1.3	5 min	**Dermal: Hands- protective gloves, coverall**
Emptying bags containing product into mixing vessel	1.1.4	5 min	**Inhalation: dust masks** Dermal: Hands- protective gloves, coveralls
Dilute product in plant	1.5.2	5 min	**None as dilution done inside plant pipe work**
Application phase			
Handling the treated timber, stacking may be done mechanically	1.1.3	Period of shift	**Dermal – gloves, coverall**
Convey treated wood to holding area, by lift truck	1.1.3	5 min	**Gloves off to drive lift truck, Potential for dermal pick-up from contaminated controls**
Post-application phase (includes disposal)			
Cleaning nozzles	1.6.1	30 min	**Dermal- hands probably not wearing gloves.**
Grease / and other maintenance tasks	1.6.1	5 min-60 min	**Hands – gloves, coverall**
Remove fallen wood from tank	1.6.1	5 min	**Dermal- gloves, coverall**
Clear sump and filters / sludge	1.6.1	Up to 60 min	**Dermal: gloves, coveralls, protective footwear, eye protection**
Sampling of treating solution	1.6.2	5 min	**Dermal: Hands- none**
Disposal – tanker, disposal of bags	1.1.3/ 1.5.2	Up to 60 min	**Dermal: Hands- protective gloves**

It should be noted that these activities i.e. 1.6.1 and disposal do not occur every day. The mixing and loading activities comprise an estimated 15 minutes per cycle, while the application activities can range from 5 minutes per cycle to an entire workday. However, it is not feasible to expect that a worker would be in direct contact with treated wood during the application phase for an entire workday. Therefore, actual exposure time for the application phase was assumed to be 4 hours, or one-half a workday. This limits the number of potential cycles for mixing and loading to 2 per day. For quantitative purposes, 0.5 hours spent daily in mixing and loading activities was assumed, and 4 hours for application.

The intermittent post-application processes can range from 45 minutes to 215 minutes (or 3.6 hours). For quantitative purposes, 1 hour daily to cover these sporadic activities was added.

Therefore, an exposure time of 5 hours daily for the application and post application phases was used.

2. Professional Users

These are referred to as post-application scenarios, in which a professional applicator receptor is exposed to borates during their application to wood items *in-situ,* at the residence or another location where the wood will be used in construction.

The professional application scenarios quantified for boric acid in this dossier are: professional spray application, professional paint application, and professional injection application. These processes were quantified based on information provided by the producers and recommendations by DGE (2002). They represent the "post-application" processes most commonly used in the borate wood preserving industry, which are likely associated with the greatest exposure, and hence risks. Any other application processes are either uncommonly used or are associated with lower exposure. To be conservative, the same assumptions were made for industrial scenarios regarding the nature and degree of potential exposure to boron. This includes a mixing and loading task in which the receptor prepares the ready-for-use mixture onsite prior to applying the material to the wood.

SPRAY APPLICATION

In this scenario, the receptor is assumed to take the product, pour it into a spray reservoir, mix it with water, and spray the solution onto wood. The wood is then allowed to dry, and then it is cut to size and used in construction at the home. Exposure can occur during the application phase through pouring and mixing, spraying, and drying of the wood (such as moving the wet wood to a storage area). During the post-application phase, exposure can occur via cutting treated wood, and handling the dried wood during construction.

PAINT APPLICATION

In this scenario, the receptor is assumed to take the product and use a power paint sprayer to apply the paint onto wood. The wood is then allowed to dry, and then it is cut to size and used in construction at the home. This is very similar to the spray application scenario. As for that scenario, exposure can occur during the application phase through opening the can, spraying, and drying of the wood (such as moving the wet wood to a storage area). During the post-application phase, exposure can occur via cutting treated wood, and handling the dried wood during construction.

INJECTION APPLICATION

No detailed information describing this scenario was located in the literature consulted (OECD, 2003, DGE, 2002, BSG, 1998). Reference was found in DGE, 2002 to "injection into woodworm holes with hand-held aerosol can"; however, no details were provided.

This particular scenario was assumed to refer to pesticides and not wood preservatives such as borate products.

Therefore, it was assumed for the purposes of evaluating the professional injection application scenario that ready-to-use borate product is introduced into timber products such as planks or posts using penetrating commercial injection apparatus. Because borate would be injected directly into the wood, exposure would be limited. Inhalation exposure would not occur as the borate product would not migrate to ambient air, and dermal exposure would largely be prevented by the direct injection method.

However, to be conservative, this scenario was evaluated assuming these exposure pathways are complete and that application methods are associated similar exposure to the professional spray and paint scenarios previously described.

The receptor is assumed to take the product, pour it into commercial injection apparatus, mix it with water, and inject the solution into wood. The wood is then allowed to dry, and then it is cut to size and used in construction at the home. Exposure can occur during the application phase through pouring and mixing, handling the application apparatus, and drying of the wood (such as moving the wet wood to a storage area). During the post-application phase, exposure can occur via cutting treated wood, and handling the dried wood during construction.

3. Non-professional Users including the general public

SPRAY APPLICATION

In this scenario, the user is assumed to take the ready-to-use product, pour it into a spray reservoir, mix it with water, and spray the solution onto wood. The wood is then allowed to dry, and then it is cut to size and used in construction at the home. Exposure can occur during the application phase through pouring and mixing, spraying, and drying of the wood (such as moving the wet wood to a storage area). During the post-application phase, exposure can occur via cutting treated wood, and handling the dried wood during construction.

Re-entry is permitted to residents as soon as the surfaces since this is a non volatile aqueous solution

PAINT APPLICATION

In this scenario, the user is assumed to take the ready-to-use product and use a power paint sprayer to apply the paint onto wood. However, the user may also brush the ready-to-use product. The wood is either treated in situ or allowed to dry, and then it is cut to size and used in construction at the home. This is very similar to the spray application scenario. As for that scenario, exposure can occur during the application phase through opening the can, spraying, and drying of the wood (such as moving the wet wood to a storage area). During the post-application phase, exposure can occur via cutting treated wood, and handling the dried wood during construction.

Exposure assumptions used to quantify exposure for these scenarios; their sources and rationales for use are provided in the following section. As noted in the preceding task tables, industrial and professional workers were assumed to wear protective clothing to mitigate both inhalation and dermal exposure during application and other processes. Amateur receptors were not assumed to wear protective clothing, but were assumed to wear appropriate clothes for such work (e.g., pants, a shirt, and shoes).

Exposure Assumptions For All Users

Assumptions were utilized in the risk assessment to estimate exposure doses of boron via the various exposure routes. These assumptions were applied to receptors for the four industrial scenarios described above. Assumptions were either universal (applied to each industrial scenario) or scenario-specific. Assumptions are either (1) default (universal) values as recommended by the regulatory guidance, (2) scenario-specific assumptions and (3) product-specific assumptions. The rationale for selection of the exposure assumptions is as follows:

The following EU guidance was consulted in compiling universal and scenario-specific assumptions:

- Assessment of Human Exposure to Biocides (BSG, 1998)
- Technical Notes for Guidance, Human Exposure to Biocidal Products, Guidance on Exposure Estimation (DGE, 2002).

Universal exposure assumptions The following assumptions were made for all industrial scenarios, from the above-cited regulatory guidance documents:

- Body weight (BW) – a standard of 70 kilos (kg) was assumed for combined adult males and females (BSG, 1998).

- Dermal surface area (SA: area of skin assumed exposed to the product) 19400 cm^2. To be conservative the entire body was assumed to be exposed. The mean value for an adult male of 70 kg was recommended by the BSG (1998) based on United States Environmental Protection Agency (USEPA, 1997) data provided in the *Exposure Factors Handbook.*

- Inhalation rate (InR). The value of 1.25 cubic meters per hour (m^3/hr) corresponds to a total of 10 m^3 per 8-hour working shift, based on data from the NONS UK 795 risk assessment (BSG, 1998). This InR can be compared to a rate of 1.3 m^3/hr for the average hourly inhalation rate for outdoor workers, published by USEPA (1997). These data indicate that the value of 1.25 m^3/hr is reasonably conservative, in that it assumes that workers are engaged in moderately intense physical labour, not only during every hour they work (i.e., the receptors are assumed to work at a consistently high rate all day), but each workday for 250 days per year, for the entire exposure duration of 25 years. This upper-bound assumption likely corresponds to very few, if any, of the actual working population in the timber preserving industry.

- Dust in air. Sawdust in air was estimated by multiplying the weight percent of boron in treated wood by a particulate level of 70 ug/m^3. This value is the highest allowable dust concentration at construction sites as promulgated by the Occupational Safety and Health Administration (OSHA) of the United States. It is unlikely that respirable dust levels in excess of those at sites undergoing heavy construction would result in the breathing zone from cutting wood. Therefore, this is likely a conservative assumption.

- Personal Protective Equipment (PPE) factors (a fraction that downwardly adjusts the exposure dose to account for mitigation of dermal and inhalation exposure to the product by PPE). The value of 0.1 (i.e., 90% reduction in exposure) was applied to all industrial and professional application scenarios based a recommendation by DGE (2002), who stated: "...an estimate of 90% exposure reduction with proper materials and proper behaviour for registration purposes can be taken as a default value for gloves and for protective clothing." (Part 2, Section 2.3). Similarly, a value of 0.5 (i.e., 50% reduction in exposure) was applied to the amateur application scenarios, as recommended by DGE (2002) for the protection offered through regular clothes without additional PPE.

- Percutaneous absorption was taken from a human study, which was designed to assess absorption of products used for wood preservation (See Doc IIIA A6.2). A The Dermal Absorption Factor (DAF) was estimated by adding one standard deviation to the mean absorption rate giving a conservative figure of 0.35% for boric acid (and, hence, boron). The dermal absorption flux was used for application and post-application scenarios, and incorporates the overall loading of boric acid in the wood. The dermal absorption factor was used for wood-in-use scenarios where only exposure to boric acid in the wood surface is relevant

Scenario-specific assumptions. The following assumptions were compiled from DGE (2002):

- Exposure time (ET; hours exposed per day). Values for the four industrial scenarios are based on scenario-specific data discussed above and the number of daily cycles as provided in Part 2, Section 8.01 of DGE, 2002.

- Exposure frequency (EF; days exposed per year). The standard upper-bound value of 250 days per year (i.e., 50 working weeks of 5 days per week) was used for the vacuum impregnation, dipping, and spraying scenarios. Based on data presented by DGE (2002), a value of 150 days was used for the deluge/flooding scenario.

- Exposure duration (ED; years exposed). The standard upper-bound occupational tenure of 25 years was used for all scenarios.

It should be noted that an EF value of 250 days/year conservatively assumes that the receptors conduct these application processes each working day; however data provided by DGE (2002) imply that exposure may occur less frequently than daily. Moreover, these processes are assumed to occur each workday for all assumed 25 working years. This upper-bound assumption likely corresponds to very few, if any, of the actual working population in the timber preserving industry.

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

Exposure Estimates

Operation	PPE	Exposure path	Body dose (mg/kg bw/d)	Repeated dose toxicity (NOAEL = 9.6 mg B/kg/day)
				MOS
Industrial Use				
automated spraying	Gloves Coverall Eye Protection (for some processes)	Dermal	2.27E-05	4.23E+05
deluge / flood process	Gloves Coverall Eye Protection (for some processes)	Dermal	1.921E-05	5.00E+05
dipping process (mechanised or manual and automated)	Gloves Coverall Eye Protection (for some processes)	Dermal	1.921E-05	5.00E+05
vacuum pressure (high or low pressure)	Gloves Coverall Eye Protection (for some processes)	Dermal	5.5E-06	1.75E+06
Professional Use				
spraying	Gloves Coverall Eye Protection	Dermal/Inhalation	5.5E-06	1.75E+06
injection;	Gloves Coverall Eye Protection (for some processes)	Dermal	5.5E-06	1.75E+06
brushing	Gloves Coverall Eye Protection (for some processes)	Dermal	5.5E-06	1.75E+06
Amatuer Use				
brushing	No Specific Protection	Dermal	5.5E-06	1.75E+06
spraying	No Specific Protection	Dermal	3.933E-06	2.44E+06
Indirect Exposure				
Sawdust	Not relevant	Inhalation	2.63E-06	2.87E+04
Dermal Contact Treated Wood	Not relevant	Dermal	3.34E-04	3.66E+06
Combined Indirect Exposures			3.37E-04	2.85E+04

2.10.2 Environmental

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

exposure towards active substance

2.10.2.1 Production

For 2 ((Borax and Etimine) of the notifiers, borates for biocidal use are not manufactured in Europe therefore are not subject to European Risk assessment. In addition the use of borates for biocidal use is an extremely minor portion (3.3%) of the overall total manufacture and use of borates. The Austrian CA will assess other production for non-biocidal uses under the ESR review. There are 5 operating sites in Europe where borates are handled in bulk that have been quantitatively assessed for the quantities of boron emissions that are released to the environment. From the data it is estimated that the losses to the environment represent between 0.002% to 0.199%. -The quantities released are detailed below.

(i) Releases into water

Quantitative data is available for four sites in Europe the total release is reported in tonnes per annum..

Site 1	Site 2	Site 3	Site 4	Boron Release (T/yr)
2.51	16.29	0.04	0.248	19.1

At a fifth site the storm waters affecting the operation are entirely recycled through the plant although a maximum limit of 2.0 ppm of Boron for any discharge to the receiving water.

(ii) Releases into air

Quantitative emission data from individual stacks is available from four European sites. The data are highly variable-.

Site 1	Sie 2	Site 3	Site 4	Boron Release (T/yr)
0.093	0.007	0.01	0.004	0.12

At a fifth site the emission level has been measured as 4.8 mg B/Nmc.

(iii) Waste disposal

Borates are mostly recycled through the plant.

Site 1	Sie 2	Site 3	Site 4	Boron Release (T/yr)
0.19	0.64	0.99	Nil	1.82

2.10.2.2 Intended use(s)

Products to be protected:

Timbers exposed to risk of attack by wood destroying organisms. For example:

Use Class 1 timbers under cover including indoor joinery (preventative)

Use Class 2 timbers under cover including indoor roofing timbers – risk of wetting (preventive)

Use Class 3 exterior timbers out of ground contact including joinery protected with a surface coating (preventive).Use Class 4a remedial application to timbers in service in ground contact e.g. boron rods inserted into utility poles which are already in service and may have been treated in the past with creosote (curative and preventive).

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Doc IIIA Section numbers 2.10.1.1/2.10.1.2/2.10.2.1/2.10.2.2

For Hazard Classes 1 & 2 emissions are not expected as indicated in OECD Series on Emission Scenario Documents No 2 for Wood Preservatives Part 1 (2002)

Affected compartment(s):

Borate is naturally present and widely distributed in the environment and are essential for the healthy development of all higher plants. Boron is essential to fish and frogs and there is some evidence to suggest that boron is essential to humans.

The partitioning coefficient for borate confirms that the greatest percentage of borate will end up in the water phase.

water

Using a Mackay Model Level 1 for boric acid >99% of the active ingredient/product will be in the water phase

sediment

Less than 1% will be distributed in sediment (Mackay model Level 1)

air

Less than 1% will be distributed in air (Mackay model Level 1)

soil

Less than 1% will be distributed in the soil compartment (Mackay model Level 1)

Predicted concentration in the affected compartment(s)

Boric acid has been used as the representative boron compound in the environmental exposure assessment. The scenarios used in the exposure assessment have been taken from the OECD Emission Scenario Document No2, Emission Scenario Document on Wood Preservatives.

water

The following environmental releases are estimated for the different process applications for boric acid (A full description of the process is contained in the Human Exposure Section)

PROCESS

Process Application	**STP (daily rate)**
Vacuum pressure	0.36 kg Boric acid
Double vacuum	0.18 kg
Automated dipping	1.8 kg
Automated spraying	*See automated dip scenario*
Industrial deluge	*See automated dip scenario*

The following releases have been estimated from the storage of treated timber. It should be noted that the model overestimates the release since for all classes of use (except Use Class 4) the timber has to be kept at a specific moisture content and will be stored undercover. The model, however, assumes that the entirety of stored treated timber is exposed to precipitation repeatedly. The assumption is made that 50% of the environmental release will be to surface water drain and 50% to soil.

Treated timber In Storage	Lost to STP in 30 days
Vacuum Pressure	1.24 kg boric acid
Double vacuum	No scenario
Automated dipping	6.18 kg
Automated spraying	*See automated dip scenario*
Industrial deluge	*See automated dip scenario*

END USE

End use scenario	Time period	Concentrati onIn water
Wood in contact with Water (fresh) jetty (UC4B)	30 days	1.8 mg /m^3

End use scenario	Using average flux valuefor period	Concentrati onin water
Sheet piling (UC4B)	30 days	630 mg/m^3

sediment

Because of the water solubility, borate released to water will not concentrate in sediment. Therefore consideration of the water media will address the sediment compartment.

air

Because of the low vapour pressure of borates release to air will be minimal.

PROCESS

Process Application	Air (daily rate)
Vacuum pressure	<0.01 kg Boric acid
Double vacuum	<0.01 kg
Automated dipping	<0.06 kg
Automated spraying	*See automated dip scenario*

soil

Because of the water solubility, > 99% of the active ingredient/product will relate to the pore water, according to the Mackay Level I model. The OECD Emission Scenario Document estimates the environmental concentrations in mg/kg of soil. However it should be noted that the released borate will be dissolved in the rain water and calculation of the soil pore water concentration is a more realistic indicator of the environmental release concentration. The low octanol/water partitioning and soil partitioning coefficient data indicate that the active ingredient/product will not preferentially concentrate in soil, but will equilibrate primarily in the water. For clarity the results are reported under soil but any risk assessment should assume that the borates are dissolved in the soil pore water.

PROCESS

Treated timber In Storage	**Soil concentration After 30 days**
Vacuum Pressure	16mg boric acid/kg wet wt soil*
Double vacuum	No scenario
Automated dipping	81 mg/kg wet wt. Soil*
Automated spraying	***See automated dip scenario***
Industrial deluge	***See automated dip scenario***

* The model assumes that all active ingredient/product will transfer to soil. Data for borate suggests this assumption is inaccurate, because of its water solubility and minimal partitioning. The concentration in soil porewater is therefore a reasonable upper bound estimate of the soil concentration.

END USE

The distances are from the treated wood and the units are in mg of boric acid/ kg wet weight of soil.

End use scenario	Time period	2.5cm	10cm (default)	50cm	100cm
Noise barrier (UC 3)	30 days	178	45	9	4
Fence (UC3)	30 days	395	99	20	10
House cladding (UC3)	30 days	494	123	24	11
Transmission pole (UC4A)	30 days	237	27	2	0.5
Fence post (UC4A)	30 days	106	22	0.7	0.3

* The model assumes that all active ingredient/product will transfer to soil. Data for borate suggests this assumption is inaccurate, because of its water solubility and minimal partitioning. The concentration in soil porewater is therefore a reasonable upper bound estimate of the soil concentration.

REMEDIAL TREATMENT- Brushing and Spraying

In the OECD ESD a default value of 5% is considered to be lost during application.

Parameter / variable	Value	Value (model default)	Origin	Additional distances	
	2.5cm	10cm	D	50cm	100cm
BAE loss per application	1,000mg	1,000mg	O	1,000mg	1,000mg
BAE Loss from wood	1680mg	1680mg	O	1680mg	1680mg
Total BAE lost	2680mg	2680mg	O	2680mg	2680mg
BAE Conc. in soil	630mg/kg*	158mg/kg	O	32mg/kg	16mg/kg

* The model assumes that all active ingredient/product will transfer to soil. Data for borate suggests this assumption is inaccurate, because of its water solubility and minimal partitioning. The concentration in soil porewater is therefore a reasonable upper bound estimate of the soil concentration.

REMEDIAL TREATMENT – Pole wrapping and Injection

Parameter / variable	Value	Value (model default)	Origin	Additional distances	
Inputs					
Distance from edge of treated wood, all dimensions increased	2.5 cm (0.025m)	10 cm	D	50 cm (0.5m)	100cm (1.0m)
Wood area below soil	1.6 m^2	1.6 m^2	D	1.6 m^2	1.6 m^2
BAE lost from 1m^2 over 30 days	1499 mg	1499mg	A	1499mg	1499mg
Wet soil volume	0.0264 m^3	0.2358 m^3	D	2.97 m^3	11.83 m^3
Bulk density of wet soil	1700 kg/m^3	1700 kg/m^3	D	1700 kg/m^3	1700 kg/m^3
Weight of soil	44.88 kg	400.86 kg	D	5,049.0 kg	20,111.0 kg
Outputs					
BAE lost from 1.6 m^2 / 30 days	2398mg	2398mg	O	2398mg	2398mg
BAE conc. in soil after 30 days	53mg/kg*	6mg/kg	O	0.5mg/kg	0.1mg/kg

* The model assumes that all active ingredient/product will transfer to soil. Data for borate suggests this assumption is inaccurate, because of its water solubility and minimal partitioning. The concentration in soil porewater is therefore a reasonable upper bound estimate of the soil concentration.

Sample table:

Table A2.10: Workplace exposure / Inhalation exposure (use addtional terminology from the TNsGs on Human exposure

Exposure scenario	Workplace operation	PPE	Year(s) of measurement	Number of measurements	Type of measurements	Exposure concentration
Production	*Emptying, filling, weighing*	*Gloves*			*personal, TWA*	
Formulation	*Cleaning*	*Protective coverall*			*area, short-term*	
Application MG../PT..	*Brushing*	*Gloves, goggles*				

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	30-Sept-05
Materials and methods	Section IIIA2.10 Human exposure assessment a. In Doc. II B Exposure Assessment for the Biocidal Product' the exposure assessment is described in section 8. Background information about the processes and values are described in Doc. III A2.10. The exposure calculation was not given, it was received from the notifier via the Board for the Authorization of Pesticides (Mail EBA, 11-05-05). b. To calculate the dermal exposure during mixing and loading and during application the notifier used the 'dermal absorption flux'. The dermal exposure was calculated by multiplying this flux (in mg/(cm^2 x hour)) with the total body surface area and with the exposure duration. The flux is derived from a dermal absorption study in volunteers (see Doc IIIA6.2). The flux (µg / (cm^2 x hour)) which is calculated here for the different active substances (a.s.), is a measure for the quantities of the different a.s. absorbed by the skin in the test concerned. This flux is a measure for the amount absorbed by the skin. However, in the exposure calculation during mixing and loading and application, it is used as measure for the amount of active substance deposited on the skin. This is not correct. Environmental exposure assessment c. Upon evaluation, the main input (use classes under consideration, dosages and leaching rates) as used in the applicant's assessment appeared to be either not relevant, incorrect or inconsistent. Therefore, RMS conducted a new environmental exposure assessment according to the OECD Emission Scenario Document for Wood preservatives. The reader is therefore referred to the environmental exposure assessment as performed by RMS, which is included in Doc IIB, Sections 8.3 and following subsections.
Conclusion	Human exposure assessment In our view, the approach in which the notifier has calculated the exposure is not correct. The calculations are therefore not provided with annotations. The exposure can be calculated by means of the models mentioned in the TNsG (2002). In the User Guidance TNsG (2002), the human exposure to wood preservatives is extensively described; to calculate the exposure to wood preservatives the most appropriate models and its parameter values are stated. The exposure to borates is calculated by using the selected models and default values for wood preservatives from the User Guidance TNsG (2002) as a guideline. Via the Board for Authorization of Pesticides (CTB) the proposal to the notifier was to calculate the exposure with this approach in addition to their own method. The notifier has done these calculations likewise (mail EBA, 09-05-05). In Doc IIB, section 8 'Exposure Assessment' the calculations which we have done are reported. In the calculations the process information given by the notifier is used as base for the calculations. Where the calculations differ from the notifier's calculations, this is mentioned. Environmental exposure assessment The above presented exposure assessment of the applicant is not considered correct. The reader is therefore referred to the environmental exposure assessment as performed by RMS, which is included in Doc IIB, Sections 8.3 and following subsections.

Reliability	3
Acceptability	Not acceptable
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document III-A: Study Summaries - Active Substance Boric Acid

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1) **3.1.1 Melting point**								X1
Melting pt. 1	No data	No data	**result:** 171°C **pressure:** No data	Value relates to heating in a closed system. When heated (in an open space) above 100°C, boric acid gradually loses water, first forming metaboric acid (HBO_2) and on further heating forms boric oxide (B_2O_3) of which the crystalline form melts at 450°C.	No data	2	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 372.	
Melting pt. 2	ASTM E 537-76 (Differential Thermal Analysis).	99.0-100.5%	**result:** No melting point detected below 1000°C. **pressure:** Atmospheric Temperature range: 25 to 1000°C.	Two endothermal peaks observed below 200°C. The first effect occurs at 97/96°C and the second effect occurs at 149/146°C. Both effects are most likely due to phase changes. Determined by Differential Thermal Analysis method.	Y	1	Cordia [redacted] 2003,	
3.1.2 Boiling point	-	-	Not Applicable.	Boiling point not applicable for boric acid, which starts to give off water and decomposes at above 100°C, first forming metaboric acid and is converted into boric oxide (B_2O_3). This has a boiling point of 2200°C.	No data	-	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 372. Greene FT and Margrave JL, J. Phys. Chem., 1966, 70, No. 7, 2112-15.	X2

3.1.3 Bulk density/ relative density								X3
Bulk/rel. density 1	No data	No data	1.5172 @ 14°C	-	No data	2	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 372.	
Bulk/rel. density 2	Test Guideline A.3 of EC Directive 92/69/EEC and TNO-PML Standard Operation Procedure Q-211-W-030. A multi-volume pyncnometer was used.	99.0-100.5%	1.489 ± 0.006 @ 23°C ±1°C	-	Y	1	Cordia J.A. [redacted] 003,	
3.2 Vapour pressure (IIA3.2)								X4
Vapour pressure 1	Test Guideline A.4 of EC Directive 92/69/EEC	99.95%	**temperature:** 25°C **result:** 9.9×10^{-6} Pa	Essentially the vapour pressure of boric acid is negligible at ambient temperatures and water vapour starts to be evolved at above 100°C because of partial decomposition.	Y	1	Tremain [redacted] 998.	
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	-	-	1.24×10^{-8} Pa m^3 mol^{-1}	Calculated from the vapour pressure of pure boric acid. Boric acid being a non-volatile inorganic material, it has a low vapour pressure and hence Henry's Constant will also be very low.	-	-	-	X5

3.3 Appearance (IIA3.3)								X6
3.3.1 Physical state			Solid					
3.3.2 Colour			White					
3.3.3 Odour			Odourless					
3.4 Absorption spectra (IIA3.4)								X7
UV/VIS	OECD Guideline 101 and TNO-PML S.O.P. Q213-W-058.	99.0-100.5%	Could not be determined.	No unusual effects were observed in running the spectra. The molar extinction coefficient of the test substance could not be determined because there were no district absorption maximum or minimum found in a neutral, basic or acidic medium.	Y	1	Cordia [redacted] 003.	
IR	TNO-PML S.O.P. Q214-W-125 version 2.	99.0-100.5%	Major peaks observed at 547, 647, 758 and 1195 cm^{-1}.	The sample was ground in KBr powder and pressed. The test substance was recorded on and FTIR-spectrometer.	Y	1	Cordia [redacted] 003.	
NMR				Study under commission. To be completed by 31st January 2005.				
MS	TNO-PML S.O.P. Q214-W-130.	99.0-100.5%	No signals characteristic of borium containing material.	A broad range of experimental conditions was used: positive and negative ions, variation of the cone voltage, variation of the flow-injection eluent and dissolution of the compounds in water or eluent. No signals produced characteristic of borium containing material.	Y	1	Cordia J.A. [redacted] 003.	

3.5 Solubility in water (IIA3.5)	*including effects of pH (5-9)*							X8
Water solubility 1	-	AR Grade.	**result:** 47.2 g/l **temperature:** 20°C **pH:** 3.7	-	N	2	Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254. Dawber JG and Matusin DH, J. Chem. Soc. Faraday Trans. 1, 1982, 78, 2521-2528.	
Water solubility 2	Test Guideline A.6 of EC Directive 92/69/EEC and TNO-PML S.O.P. Q213-W-036.	99.0-100.5%	**result:** 49.20 ± 0.35 g/l **temperature:** 20.0 ± 0.5 °C **pH:** 3.76 ± 0.22	The difference between the determined water solubility and the literature value (47.4 g/l) could be explained by the fact that the two protocol methods used in each case were different.	Y	1	Cordia [redacted] 2003	
Water solubility 3				Further study under commission to cover variation in solubility with pH. To be completed by 31st January 2005.				

3.6	**Dissociation constant (-)**	-	99.0-100.5%	pK_a = 9.23	Dissociation constant (acid constant, ionisation constant) of boric acid: Boric acid (orthoboric acid), molecular formula $B(OH)_3$, is a Lewis acid (i.e., a hydroxide ion acceptor) rather than a Bronsted acid (proton donator). $B(OH)_3$ (aq) + $2H_2O$ (l) = H_3O^+ + $B(OH)_4^-$ (A) Raman spectroscopy and ^{11}B NMR support such a dissociation (ionisation) mechanism. The equilibrium constant for the above dissociation reaction (i.e., the acid constant, K_a, of boric acid) is reported to be 5.80×10^{-10} mol L^{-1}. $pK_a = -\log_{10}K_a$, = 9.23 A well as being a very weak acid, as discussed above, boric acid is exclusively a monobasic acid. Thus there is only one acid constant. The equilibrium constant for the reaction (A) is small enough that the proportion of boric acid in near neutral pH dilute solutions is greater than 99%. The relative concentration of its conjugate base, the tetrahydroxyborate anion, increases with increasing pH and becomes the dominant species above roughly pH 9.	N	2	R. P. Bell *et al.*, *Chem. Boron Its Compounds*, 1967, 209-21 and A. Kankaanpera *et al.*, *Acta Chem. Scand.* **23**, No. 2, 712 (1969). H. O. Jenkins, *Trans. Faraday Soc.* **41**, 138 (1945	X9

3.6	**Dissociation constant (-)**	No data	No data	pKa = 9.15		No data	2	WHO, 1998, Guidelines for drinking water quality. 2nd Edition Addendum to Volume 2 Boron page 15. World Health Organisation, Geneva	
3.7	**Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)**	No data	No data	**Glycerol (98.5%) = 19.9 x 10^4 mg/l @ 20°C** Acetone = 6 x 10^3 mg/l @ 25°C Methanol = 22.6 x 10^4 mg/l @ 25°C	-	No data	2	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 375.	X10
3.8	**Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)**	-	-	Not required.	-	-	-	-	X11
3.9	**Partition coefficient n-octanol/water (IIA3.6)**	*including effects of pH (5-9)*							X12
log Pow 1		-	No data	**result:** -0.7570 **temperature:** 25°C	-	No data	2	Barres M, Rev. Chim. Miner., 1967, 4, 803-838; Chem. Abstr., 1968, 69, 30628.	
log Pow 2		Test Guideline A.8 of EC Directive 92/69/EEC and TNO PML-S.O.P. Q213-W-051.	99.0-100.5%	**result:** -1.09 ± 0.16 **temperature:** 22°C ± 1°C. **pH:** 7.5	The difference between the determined value and the literature value (-0.7570 @ 25°C) is reasonable. The temperature can give an error of max. 0.01 log P_{ow} value.	Y	1	Cordi [redacted] 2003.	

3.10	**Thermal stability, identity of relevant breakdown products (IIA3.7)**	-	-	-	Boric acid is stable up to approximately 75°C. It dehydrates on further heating to form metaboric acid and then boric oxide: $B(OH)_3 = HBO_2 + H_2O$ (Temperature range 120 to 180°C) $HBO_2 = 0.5\ B_2O_3 + H_2O$ (Temperature range 180 to ~400°C). Boric oxide and metaboric acid will convert to boric acid on contact with water or on exposure to moist air. Rapid heating to ~250°C may cause boric acid to melt. During heating, a small quantity of boric acid can evaporate with the evolved water vapour. This will be visible as white fumes of condensed boric acid as the gas cools.	-	2	-	X13
3.11	**Flammability, including auto-flammability and identity of combustion products (IIA3.8)**	-	-	Not applicable.	Non-flammable solid. Flammability classification (USA) 29CFR 1910.1200. The product is used as a flame retardant.	-	-	-	X14
3.12	**Flash-point (IIA3.9)**	-	-	Not applicable.	Non-flammable solid. The product is used as a flame retardant.	-	-	-	X15

3.13 Surface tension (IIA3.10)								X16
Surface tension 1	Surface tension measurements determined with a Cenco Model No.70545 DuNuoy type Interfacial Tensiometer.	Borax tetraborate pentahydrate (~100%)	**result:** 71.0 ±0.4 mN/m **temperature:** 23°C **concentration:** 0.3g/l		N	2	Wurster [redacted] 1963.	
3.14 Viscosity (-)	-	-	Not applicable.	Solid substance.	-	-	-	
3.15 Explosive properties (IIA3.11)	-	-	Not applicable.	The standard heat of formation of crystalline orthoboric acid is -1094.3 kJ/mol. Boron forms particularly strong covalent bonds with oxygen.	-	2	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 1992, 4th Edition, Volume 4, page 373.	X17
3.15 Explosive properties (IIA3.11)	CTL SOP 201 (Dust Cloud Flammability)	>99.9%	Negative	Did not produce an explosion when in the form of a dust cloud. Potential heat sources (up to 1000°C) and electrostatic discharges will not cause the material to ignite.	Y	1	Chilworth Technology [redacted] 2003.	

3.15	**Explosive properties (IIA3.11)**	-	-	-	Potential explosive properties are indicated by the presence of certain reactive groups in the molecule. The molecular structure of none of the substances indicates that such groups are present. No reactive or instable groups are present. The molecular structure does not indicate that these substances will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC. Conclusion: Considering the molecular structure and the information that is available in the literature, boric acid is not expected to have explosive properties in the sense of EC Directive 92/69/EEC.	-	1	Mak [redacted] 2004 [redacted]	

3.16	**Oxidizing properties (IIA3.12)**	-	-	-	In principle, inorganic substances that contain oxygen may show oxidizing properties and these should therefore be tested according to Test Guideline A.17 of EC Directive 92/69/EEC. However, a search of available literature has not resulted in any indication of oxidizing properties, neither has it shown any accident data that may be attributed to oxidizing properties. Conclusion: Considering the molecular structure and the information that is available in the literature, boric acid is not expected to have oxidizing properties in the sense of EC Directive 92/69/EEC.	-	1	Mak [redacted] 2004. [redacted]	X18
3.17	**Reactivity towards container material (IIA3.13)**	Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene) Unsuitable container materials: Base metals							X19

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.1.1. Melting point a. Two studies were summarized by the notifier without indication which study was considered as key study. Study 1 (Kirk-Othmer) is an encyclopedia without any indications on methods. The melting point value of 171 °C from this study was however used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). The value is based on a closed system with unknown pressure, whereas the value should be based on atmospheric pressure. Therefore, the study is given reliability 4. Study 2 (Cordia et al., 2003) is considered as key study by the RMS because this study was carried out under GLP according to EC method A1 (= ASTM E 537-76) and with known purity. b. Although GLP was indicated for the key study, the report submitted, did not contain any authorisation signatures. An authorised report is not required as GLP itself is not a hard requirement.. c. Experiments were carried out with batch number 225-01-442[redacted]. Purity specification ranges from 99.0 to 100.5%. The purity of the active substance differs from the minimum purity indicated in chapter IIIA2.7 as indicated by the notifier. Maximum purity cannot be higher than 100%. Data on impurities are not available. d. The reference is stated wrong in the table. The full reference for the key study should be stated as: [redacted]
Conclusion	Not applicable. No melting point can be defined because of decomposition of the active substance. Phase transitions are found at 97/96 °C and 149/146 °C. Upon heating boric acid loses water, first forming metaboric acid (HBO_2) and than boric oxide (B_2O_3). For boric oxide no melting point is found in the range 25-1000 °C. study 1 is reliability 4; study 2 is reliability 1 (key study)
Reliability	
Acceptability	Acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29-Apr-05
Materials and methods	Section 3.1.2. Boiling point. a. Two studies were summarized by the notifier without indication which study was considered as key study. The first study (Kirk-Othmer) is an encyclopedia and states that when heated slowly boric acid starts to give off water and is first converted into metaboric acid (HBO_2) and second into boric oxide (B_2O_3). The boiling point value for B_2O_3 is however given as 2316 °C. In the second study (Greene and Margrave, 1996) a boiling point of 2475 K was deduced for boric oxide (B_2O_3). None of the studies is considered reliable enough to be a key study by the RMS. None of the studies was carried out according to GLP nor according to OECD guidelines. Purity data are not indicated. The reliability is set at 4 for both studies. b. That a boiling point is not applicable, can be deduced from the melting point study (section A3.1.1) where no melting point was found in the range 25-1000 °C. Phase transitions were found at 97/96 °C and 149/146 °C. Therefore additional data are not required. c. In the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env.hh) it was concluded from study 1 that a boiling point for boric acid was not applicable because boric acid decomposes at 100 °C first forming metaboric acid and is converted into boric oxide.
Conclusion	Not applicable. No boiling point can be defined because of decomposition of the active substance. Phase transitions were found at 97/96 °C and 149/146 °C. Upon heating boric acid loses water, first forming metaboric acid (HBO_2) and than boric oxide (B_2O_3). For boric oxide no melting point was found in the range 25-1000 °C. study 1 and study 2 set at reliability 4.
Reliability	acceptable
Acceptability	
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.1.3. Relative density. a. Two studies were summarized by the notifier without indication which study was considered as key study. Study 1 (Kirk-Othmer) is an encyclopedia without any indications on methods and is given reliability 4. The relative density value of 1.5172 from this study was however used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). The value is determined at 14 °C, whereas the value should be based on 20 °C. Therefore, the study is given reliability 4. Study 2 (Cordia et al., 2003) is considered as key study by the RMS because this study was carried out under GLP according to EC method EC method A3 (pycnometer method) and with known purity. b. Typing error: "a multi-volume pyncnometer" should be "a multi-volume pycnometer" c. Although GLP was indicated for the key study, the report submitted, did not contain any authorisation signatures. An authorised report is not required as GLP itself is not a hard requirement.. d. Experiments were carried out with batch number 225-01-442 [redacted] Purity specification ranges from 99.0 to 100.5%. The purity of the active substance differs from the minimum purity indicated in chapter IIIA2.7 as indicated by the notifier. Maximum purity cannot be higher than 100%. Data on impurities are not available. e. The physical state of the measured substance is a solid. f. The relative density to water at 4 °C was calculated by dividing the absolute density with 1000.00 kg/m^3. The relative density is expressed as D^{23}_4, whereas it should be expressed as D^{20}_4. According to the notifier for solids the D^{23}_4 is equal to the D^{20}_4 within the experimental error. This is considered acceptable by the RMS. g. The reference is stated wrong in the table. The full reference for the key study should be stated as: [redacted]

Conclusion	Relative density $D^{23}_4 = 1.489 \pm 0.006$
Reliability	study 1 reliability 4, study 2 reliability 1 (key study)
Acceptability	acceptable.
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.2. Vapour pressure. a. The notifier submitted one study (Tremain, 1998), which is considered as key study. b. Experiments were carried out with batch number 161-98-364 [redacted]. Full specifications are given for the active substance and for the impurities. The purity of the active substance (99.95%) complies with the minimum purity for the Borax Europe Ltd product (99.9%) but differs from the minimum purity indicated in chapter IIIA2.7 for the Etimine s.a. product (100%). c. Vapour pressure was measured using EEC method A4 (effusion method, vapour pressure balance) which is suitable for the range 10^{-3} to 1 Pa. The vapour pressure indicated (9.9×10^{-6} Pa) lies outside this range. Therefore the RMS considers the value as not reliable. Although the gas saturation method or the spinning rotor method would have been preferred instead (suitable in the range 10^{-4} to 0.5-1 Pa), there are no methods to measure vapour pressures below 10^{-4} Pa. d. Temperature readings were taken in four runs at temperatures between 111-160 °C. These temperatures lie all above the first phase transition point of 97/96 °C, where water vapour starts to be evolved. By extrapolation from the temperature range 111-160 °C the vapour pressure of metaboric acid has been determined instead of that of boric acid. According to EEC method A4, vapour pressure readings should be taken at 10-20 °C below and 10-20 °C above the transition point. The balance readings were too low and too variable for a line of best fit to have any meaning. Therefore, extrapolation to 25 °C is considered not appropriate here. Because of the very low vapour pressures found for metaboric acid, and because the vapour pressure of boric acid is expected to be even lower than metaboric acid, additional data are not required. e. The full reference for the key study should be stated as: [redacted] f. In the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env.hh) another reference (Mellor's Comprehensive) was used to calculate a vapour pressure of 9.9×10^{-6} Pa. This value could however not be found in this reference.
Conclusion	Not applicable. Experimental data indicate that the vapour pressure is less than 10^{-5} Pa at ambient temperature.
Reliability	as indicated by the notifier.
Acceptability	acceptable.
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.1.1, Henry's law constant Henry's law constant is indicated without further reference or way of calculation. The Henry's law constant can only be derived from the vapour pressure in combination with the aqueous solubility. The value is considered not reliable by the RMS, because the vapour pressure for boric acid is expected to be less than 10^{-5} Pa. No additional data are required.
Conclusion	Not applicable. Experimental data indicate that the vapour pressure is less than 10^{-5} Pa at ambient temperature.
Reliability	as indicated by the notifier.
Acceptability	acceptable.
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.3 Appearance a. Physical state, color and odour is stated without specification of the purity of the active substance, impurities present, temperature and pressure. b. Physical state corresponds with data in the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). as indicated by the notifier
Conclusion	as indicated by the notifier.
Reliability	acceptable
Acceptability	-
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.4 Spectra a. Two studies were submitted. Study 1 contains data and is considered as key study by the RMS because GLP is indicated and data were obtained according to guidelines. Study 2 is a statement on NMR, which was submitted at a later stage. This study was not summarized by the notifier. The study is given reliability of 4. b. Although GLP was indicated for study 1, the report submitted, did not contain any authorisation signatures. An authorised report is not required as GLP itself is not a hard requirement.. c. UV/VIS, IR and MS experiments in the key study were carried out with batch number 225-01-442 [redacted] Purity specification ranges from 99.0 to 100.5%. The purity of the active substance differs from the minimum purity indicated in chapter IIIA2.7 as indicated by the notifier. Maximum purity cannot be higher than 100%. Data on impurities are not available. d. UV/VIS spectra were recorded between 190-500 nm. According to OECD 101 guideline, the spectrum should be recorded between 200-750 nm. The recording was stopped too early. But for a salt like boric acid without absorption in the area between 190-500 nm, an absorption in the area between 500-750 nm is not to be expected. e. FTIR spectra were recorded between 400-4000 cm^{-1}. Peaks were observed at 547 (narrow), 647 (narrow), 676 (narrow), 758 (broad), 884 (narrow), 1195 (narrow), 1462 (broad), 2251 (narrow), 2362 (narrow), 2513 (narrow), 3184 (broad) cm^{-1}. f. In the notifier's overview the only information given on NMR is that a study is to be completed. This information was submitted at a later stage, but a new notifiers' summary was not submitted. In this study 2, a statement was given that ^{13}C-NMR spectra are not applicable, because boric acid does not contain carbon atoms. The study is given reliability of 4. Although ^{11}B-NMR or ^{17}O-NMR are more appropriate, these instruments are not available in most laboratories. g. MS data could not be obtained when an instrument designed for organic substances was used (HPLC-MS, flow injection, electrospray, Q-TOF).

	h. Another technique which is appropriate to elucidate the structure of boric acid is Raman spectroscopy or X-ray spectroscopy. Spectral data for these techniques are welcome. See: Bell et al. 1969, submitted for IIIA3.6. i. The reference is stated wrong in the table. The full reference for the key study should be stated as: [redacted] j. The NMR reference is not stated in the table. The full reference for the NMR statement study should be stated as: [redacted]
Conclusion	as indicated by the notifier.
Reliability	acceptable
Acceptability	Raman spectroscopy and X-ray spectroscopy data are desirable.
Remarks	

	Comments from ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	14-Sept-05
Materials and methods	Section 3.5 Water solubility. a. Four studies were submitted by the notifier, of which only three studies were summarized by the notifier without indication which study was considered as key study. Study 1 (Mellor's Comprehensive) is an encyclopedia. The water solubility value of 47.2 g/L from this study was used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). Because no methods are indicated, the reliability is set at 4. Study 2 (Dawber and Matusin, 1982) focusses on the dissociation constant in the presence of polyols and is not relevant. Study 2 is set at a reliability of 4. Study 3 (Cordia et al., 2003) is considered as key study by the RMS because this study was carried out under GLP according to EC method A6 (flask method) and with known purity. Study 4 (Spruit, 2005) was submitted at a later stage and contained information on solubility at different pH values. This study was not summarized by the notifier but is summarized here by the RMS. b. Although GLP was indicated for the key study (study 3), the report submitted, did not contain any authorisation signatures. An authorised report is required. c. Experiments in the key study (study 3) were carried out with batch number 225-01-442[redacted]. Purity specification ranges from 99.0 to 100.5% The purity of the active substance differs from the minimum purity indicated in chapter IIIA2.7 as indicated by the notifier. Maximum purity cannot be higher than 100%. Data on impurities are not available. d. The solubility in the key study (study 3) was determined by EC method A6 (flask method) and samples were analysed by HPLC with refractive index detection. A solution of boric acid in water gets a pH of 3.76. e. The reference is stated wrong in the table. The full reference for the key study should be stated as: [redacted] f. The key study determines the water solubility by dissolving the substance in water (resulting pH=3.76), whereas the effect of pH (5 to 9) must be studied. In the Kirk-Othmer encyclopedia (submitted under IIIA3.1.1) a temperature dependence of water solubility is indicated. Therefore also the effect of temperature on the water solubility must be studied. g. A fourth study was submitted at a later stage to fulfil these data gaps and was not summarized by the notifier. The reference is not stated in the table. The full reference for this study is [redacted] h. Although GLP was indicated for the fourth study, the report submitted, did not contain any authorisation signatures. The fourth study is considered as second key study. An authorised report is required. i. Experiments in the fourth study were carried out with batch number BRt3001B ([redacted] The purity of the active substance is given as 99.9%. Data on impurities are not available. j. The solubility in the fourth study was determined by EC method A6 (flask method) and samples were analysed by HPLC with refractive index detection.

	k. Water solubility in the first key study (study 3) was 49.2 ± 0.35 g/L at 20 ± 0.5 °C in unbuffered water, resulting in a pH of 3.76. Water solubility in the second key study (study 4) was 48.07 ± 0.83 g/L at 20 °C in unbuffered water, resulting in a pH of 3.85-4.08. The mean value for both these studies is 48.6 ± 0.90 g/L at 20 °C. Values for 10 and 30 °C are presented in the conclusions. l. To determine the water solubility at pH=7 and 9, a Na/K phosphate buffer and tris-HCl buffer was used respectively. But upon dissolution the pH changed to 5.6-5.7 indicating insufficient buffering capacity. The molarity of the phosphate and tris buffers was not indicated, but borate itself is a very powerful buffer. Further, the solubility of boric acid is influenced by the ion-pair formation that occurs in the presence of alkali-metal ions (e.g. Na, K) . Therefore, the determination of water solubility at other pH-values is not possible and no further studies are required.
Conclusion	The most recent GLP study (Spruit, 2006) is used for water solubility results in the LOEP. Water solubility is (average of 3 measurements): 36.24 ± 1.03 g/L at 10 °C (pH of the test solution 3.91 - 3.95) 48.37 ± 0.62 g/L at 20 °C (pH of the test solution 3.61 - 3.62) 62.54 ± 0.81 g/L at 30 °C (pH of the test solution 4.36 – 4.46) 54.13 ± 0.75 g/L in pH 7 KH_2PO_4 buffer at 20 °C (pH of the test solution 5.60 – 5.69) 62.95 ± 1.47 g/L in pH 9 tris buffer at 20 °C (pH of the test solution 5.64 – 5.69) 66.38 ± 0.13 g/L in pH 9 ammonium carbonate buffer at 20 °C (pH of the test solution 5.96 – 6.01) Water solubility studies at pH > 6 are not possible because of the strong buffering capacity of boric acid solutions and ion-pair formation in the presence of alkali-metal ions like Na, K.
Reliability	study 1 (Mellor's Comprehensive), set at 4. study 2 (Dawber and Matusin), set at 4. study 3 (Cordia et al., 2003), set at 1 (key study) study 4 (Spruit, 2006), set at 1 (key study)
Acceptability	Acceptable.
Remarks	Please note that in the final report Spruit, 2006 (study 4), data differs from data summarised in the previous version of the CAR.

Comments from ...

Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	**EVALUATION BY RAPPORTEUR MEMBER STATE** 29-Apr-05
Materials and methods	Section 3.6 Dissociation constant. a. For the determination of the dissociation constant, five studies were submitted by the notifier without indication which study was considered as key study. None of the studies is considered reliable enough to be a key study by the RMS. Two of the studies submitted were not summarized by the notifier: Hahn and Klockman, 1930 and Kankaanpera and Salomaa, 1969. Hahn and Klockman, 1930, and Jenkins, 1945 give a theoretical calculation model for the dissociation constant of boric acid and metaboric acid (HBO_2) respectively. Calculated values for these compounds are not reported and experimental values are not available. The reliability is set at 4. Bell et al, 1967 and Kankaanpera and Salomaa, 1969 review on the structure of the borate ions. The structures found with Raman spectrometry and NMR were the uncharged $B(OH)_3$ and $[B(OH)_4]^-$. Boron concentration was however not indicated. The dissociation constant for this equilibrium was reported as pKa=9.2. Methods were however not indicated and the reliability is set at 4 for both studies. WHO, 1998 reports a pKa= 9.15 in dilute aqueous solutions of boric acid. Methods were however not indicated and the reliability is set at 4. Although the notifier indicates a purity of 99.0 to 100.5%, no purity indications are given in the study reports cited above. b. The references from document IIIA6.2-A10 read across for **boric oxide** contained additional information on dissociation constants. This information is summarized by the RMS here: Ingri, 1963 investigated the behaviour of boric acid at different pH values and different ion strengths at 25 °C using potentiometric titration with hydrogen or glass electrodes. The author concluded that in acid solution at pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At intermediate pH-values, for B ≤ 0.025 M, a mixture of $B(OH)_3$ and $B(OH)_4^-$ was found and for B > 0.025 M also polynuclear complexes were found. In an inert medium of 3 M $Na(ClO_4, OH)$ or 3M Na(Br) or 3M Li(Br), polynuclear $B_3O_3(OH)_4^-$ was found and both $B_3O_3(OH)_5^{2-}$ and $B_4O_5(OH)_4^{2-}$. When the medium was changed into 3 M K(Br) the $B_3O_3(OH)_5^{2-}$ complex was not formed. In a self-medium of 3 M $Na(B(OH)_4, OH)$ at alkaline pH-values the polynuclear $B_4O_5(OH)_4^{2}$ was found in addition to small amounts of $B_3O_3(OH)_5^{2-}$. In an inert medium of 0.1 or 3 M $Na(ClO_4, OH)$ and at high boron concentrations mainly $B_5O_6(OH)_4^-$ was found. Therefore, at pH-values between 5-12, an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3$ ↔ polynuclear anions ↔ $B(OH)_4^-$. At low boron concentrations (B ≤ 0.025 M) the equilibrium changes into $B(OH)_3$ ↔ $B(OH)_4^-$. For the latter equilibrium a pK_a value of 9.00 ± 0.05 was obtained at 25 °C. At higher boron concentrations the other species must be taken into account. Ingri, 1963 determined equilibrium constants for each of the species. The disscociation constants for the polynuclear anions require complex formulas and are considered not relevant for the present evaluation. The reliability is set at 2 for this study. In Maeda, 1979, Raman spectra were taken from 1.5 M boron solutions with pH values of 6.4 - 7.4 - 8.3 - 9.4 obtained by mixing appropriate amounts of boric acid and sodium hydroxide. At all pH values, both $B(OH)_3$ and $B(OH)_4^-$ were present as well as three different polyborate ions: $B_5O_6(OH)_4^-$, $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$. In Farmer, 1982, an overview is given on borate dissociation studies.

Because no methods are indicated, the reliability is set at 4. The study can only be used as background information.
Based on NMR data, the reactions can be described as the interaction of boric acid with the borate anion:
a. $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa1 = 9.0
b. $4B(OH)_3 + [B(OH)_4]^- \leftrightarrow [B_5O_6(OH)_4]^- + 6H_2O$ pKa5 = 6.8
c. $2B(OH)_3 + [B(OH)_4]^- \leftrightarrow [B_3O_3(OH)_4]^- + 3H_2O$ pKa2 = 6.8
d. $2B(OH)_3 + 2[B(OH)_4]^- \leftrightarrow [B_4O_5(OH)_4]^{2-} + 5H_2O$ pKa4 = 14.8
e. $B(OH)_3 + 2[B(OH)_4]^- \leftrightarrow [B_3O_3(OH)_5]^{2-} + 3H_2O$ pKa3 = 16.5
Borate equilibrium constants are influenced by group I metal salts (Na, K, Cs) and temperature. In the presence of NaCl, Ka1 becomes larger and Ka4 smaller as temperatures increase. With increasing size of hydrated cation (Na, K, Cs) Ka1, Ka2 and Ka4 increase. Maximum values of Ka1, Ka2, Ka3, Ka4 are reached in saturated salt solutions.
Raman spectroscopy confirmed the structures in aqueous solutions. At pH=4.2 only boric acid was found. At pH=11 $B(OH)_4^-$ was found and a slight amount of polyanions (unresolved broad band). At pH=8.3 boric acid, $B(OH)_4^-$ as well as polyanions $[B_3O_3(OH)_4]^-$, $[B_4O_5(OH)_4]^{2-}$, $[B_5O_6(OH)_4]^-$ and $[B_3O_3(OH)_4]^-$ were found. No evidence of $B_3O_3(OH)_5]^{2-}$ was found.
In the presence of metal ions (e.g. Na, Mg, Sr, Ba, Ca, Fe) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration. For the equilibrium $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ logarithmic dissociation constants of -1.63, -1.80, -1.56, -1.50 and -0.22 were found for M= Mg, Ca, Sr, Ba and Na.
In Encyclopedia, Kirk-Othmer, 1992, the equilibrium constant for dilute solutions of boric acid (<0.1 M) for the equilibrium of $B(OH)_3 + 2\,H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ is reported to be 5.8×10^{-10} at 25 °C. This corresponds to a pKa value of 9.24. Calculated pH values based on this constant deviate considerably from measured ones as the boric acid concentration is increased, as is shown in the table. Methods were however not indicated and the reliability is set at 4.

B(OH)3 conc	pH observed	pH calculated
0.0603 M	5.23	5.23
0.0904 M	5.14	5.14
0.1205 M	5.01	5.08
0.211 M	4.71	4.96
0.422 M	4.22	4.80
0.512 M	4.06	4.76
0.753 M	3.69	4.54

In textbook, Holleman, 1995, the dissociation constant is reported as pKa = 9.25 for a diluted solution of boric acid. Methods were however not indicated and the reliability is set at 4.
In study report, De Vette, 2001, Raman spectroscopy was used to identify species in 0.02 M boron solutions of boric acid, disodium tetraborate decahydrate and disodium octaborate tetrahydrate in non-buffered and buffered solutions at pH 6.0, 7.0, 8.0 and 9.0. In all solutions prominent peaks for undissociated $B(OH)_3$ were found. Depending on pH also peaks for $B(OH)_4^-$ and polyborate anions were found.

References

Ingri N. Equilibrium studies of polyanions containing B^{III}, Si^{IV}, Ge^{IV} and V^V. Sven. Kem. Tidskr. 1963;75(4):199-230.

Maeda M, Raman Spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)

Farmer, 1982 Structural Chemistry in the Borate Industry., Chem and Ind.,

Kirk – Othmer Encyclopedia of Chemical Technology, V4, 1992, pp 378-380

Holleman, 1995. Lehrbuch der anorganischen Chemie. 101st ed de Gruyter, Berlin, copyright

	De Vette, [redacted] 2001 [redacted]
Conclusion	c. None of the studies was carried out according to OECD 112. The study of Ingri, 1963 is considered as key study and together with the other studies a good overview is obtained about processes occurring when boric acid is dissolved in water. d. In the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh) a dissociation constant of 7.3×10^{-10} was stated, this corresponds to a pKa of 9.14. This value is based on a theoretical calculation from Hahn and Klockman, 1930. The reliability is set at 4. At low boron concentrations ($B \leq 0.025$ M) the following equilibrium is found $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25 °C In dilute aqueous solutions ($B \leq 0.025$ M) boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 7, at pH > 11 the metaborate ion $[B(OH)_4]^-$ becomes the main species in solution. At inbetween values (pH 7-11) both species are present. At higher boron concentrations (B > 0.025 M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. In acid solution at pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At inbetween values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends upon temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide. Reliability is set at 4 for all studies, except Ingri, 1963 set at 2.
Reliability	acceptable
Acceptability	-
Remarks	

Comments from ...

Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21-Feb-05
Materials and methods	Section 3.7 Solubility in organic solvents. a. One study was summarized by the notifier. The study (Kirk-Othmer) is an encyclopedia without any indications on methods and is given reliability 4. b. The same solubility values of 199 g/L in glycerol, 6 g/L in acetone, 226 g/L in methanol were used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). Values came from another reference: [redacted] not submitted for the present evaluation.
Conclusion	No additional data required as a new study would not be essential for the risk assessment of boric acid.
Reliability	N/A
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27-Jan-05
Materials and methods	Section 3.8 Stability in organic solvents Data are not required because the active substance does not contain any organic solvents.
Conclusion	as indicated by the notifier
Reliability	as indicated by the notifier.
Acceptability	acceptable.
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.9 Partition coefficient. a. Two studies were summarized by the notifier without indication which study was considered as key study. Study 2 (Cordia et al., 2003) is considered as key study by the RMS because this study was carried out under GLP according to EC method A8 and with known purity. Study 1 (Barres, 1967) is given reliablity 2 because the study was not carried out under GLP. b. Although GLP was indicated for the key study, the report submitted, did not contain any authorisation signatures. An authorised report is not required as GLP in itself is not a hard requirement. c. Experiments in the key study were carried out with batch number 225-01-442 [redacted] Ltd. Purity specification ranges from 99.0 to 100.5%. The purity of the active substance differs from the minimum purity indicated in chapter IIIA2.7 as indicated by the notifier. Maximum purity cannot be higher than 100%. Data on impurities are not available. d. The key study was carried out with the shake flask method. Concentrations in the samples were determined by HPLC with refractive index detection. Boric acid was dissolved in a potassium/sodium phosphate buffer pH=7.5 at 22 °C at a concentration of 0.5972 g/L (0.00966 M boron). At concentrations below 0.025 M boron an equilibrium is formed between $B(OH)_3$ and $B(OH)_4^-$. The estimated pK_a value for this equilibrium is 9.0 (see IIIA3.7) and at pH=7.5 boric acid will be present at approximately 97% in the non-ionized form $B(OH)_3$ and for 3% in the ionized form. Possibly the $B(OH)_3$ concentration is reduced because of ion pair formation between potassium or sodium and the $B(OH)_4^-$ ions. e. The alternate study (Barres, 1967) was carried out with the shake flask method. Concentrations in the samples were determined by electrometry. Boric acid, analytical grade, was recrystallized to unknown purity. Boric acid was dissolved in decarbonated water without buffer system at 25 °C at various concentrations. Upon equilibrium concentrations in the aqueous phase varied between 0.16 - 0.89 M boron. At boron concentrations above 0.025 M, an equilibrium is formed between $B(OH)_3$, $B(OH)_4^-$ and polyborate anions. The resulting pH value was not measured. The log Pow value found (-0.757 ± 0.004) was independent of boric acid concentration. The partition coefficient value of -0.757 from this study was used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). f. In the alternate study (Barres, 1967) the log Pow value was found to be dependant upon the salt concentration in the aqueous solution and on temperature: log Pow = -0.757 in water at 25 °C log Pow = -0.742 in 2 M KCl at 25 °C log Pow = -0.561 in 3 M $NaClO_4$ at 25 °C log Pow = -0.554 in 3 M $NaClO_4$ at 35 °C It was found that in a $B(OH)_3$-$NaB(OH)_4$ or $B(OH)_3$-$KB(OH)_4$ system, undissociated boric acid was the only compound extracted into octanol. g. The value found in the key study (-1.09 ± 0.16 at 22 °C) differs from the value found in the alternate study (-0.757 ± 0.004 at 25 °C). The notifier indicates that the temperature can give an error of maximum 0.01 log-unit, but this effect may actually be somewhat larger. At least no proof is given for this statement. The difference between the two values is probably caused by differences in boron concentration (> 0.025 M in alternate study, <0.025 M in key study) and differences in the solvent (decarbonated unbuffered water in alternate study, sodium or potassium phosphate buffer in key study).

	h. The difference between log Pow values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log Pow unit. No further tests are required. i. The reference is stated wrong in the table. The full reference for the key study should be stated as: [redacted]
Conclusion	log Pow = -0.561 to -1.09 at 22-25 °C, depending on the presence of metal ions (e.g sodium or potassium from buffered systems) and boron concentration..
Reliability	as indicated by the notifier for study 2.
Acceptability	acceptable.
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	14-Sept-05
Materials and methods	Section 3.10 Thermal stability. a. The notifier did not submit any studies, but gave a description of the phase transitions that take place in the temperature range 75-400 °C. No references are stated to confirm this statement. b. The reaction equation $HBO_2 \leftrightarrow 0.5\ B_2O_3 + H_2O$ is not correct. This should be: $2\ HBO_2 \leftrightarrow B_2O_3 + H_2O$ c. Boric acid is considered stable under the conditions normally required for a storage stability test (14 days at 54-55 °C, OECD guideline 113). No further studies are required.

Conclusion	as indicated by the notifier
Reliability	reliability set at 4.
Acceptability	acceptable
Remarks	-

	Comments from ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.11 Flammability. a. The notifier submitted a flammability test under section 3.15 which can be used as key study with reliability of 2. A small amount of boric acid is placed on a spatula and heated over a Bunsen burner. The sample melts to a clear liquid and emits small quantities of grey smoke, which ignites with a small, green, non-sustaining flame. On completion of testing a white material remains. From this preliminary test it can be concluded that boric acid is a non-flammable solid and further tests are not required. This same conclusion was drawn in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh) b. Experiments in the key study were carried out with batch number S013403 [redacted] Data on the purity of the active substance and on impurities are not available. c. The full reference for the key study is: [redacted]

Conclusion	boric acid is a non-flammable solid
Reliability	reliability is set at 2.
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21-Feb-05
Materials and methods	Section 3.12 Flash point. In the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh) it was concluded that flash point is not applicable for solids.
Conclusion	not applicable, because boric acid is a non-flammable solid
Reliability	-
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15-Feb-05
Materials and methods	Section 3.13 Surface tension. a. The notifier submitted one study (Wurster, 1963) where disodium tetraborate pentahydrate was dissolved in water. The study is considered not reliable enough to be a key study by the RMS. The study was not carried out according to GLP nor according to EC guidelines. Purity data are not indicated. The study can be used as indication study (reliability 4). b. For a 3% (w/v) solution of disodium tetraborate pentahydrate, a surface tension of 69.5-71.0 dynes/cm or mN/m was found at 23-24 °C, slightly lower than the surface tension for water (72.8 at 20 °C). Although the surface tension for a solution of disodium tetraborate pentahydrate will be slightly different from the surface tension for a solution of boric acid because of the additional sodium ions, surface tension is considered not applicable for inorganic substances. No further data are required.
Conclusion	Surface tension is considered not applicable for inorganic substances. Boric acid is an inorganic substance and the surface tension of a solution in water will be slightly lower than the surface tension for water (72.8 mN/m at 20 °C). reliability is set at 4.
Reliability	acceptable
Acceptability	-
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14-Sept-05
Materials and methods	Section 3.15 Explosive properties. a. The notifier submitted three studies which are all relevant for assessment. Study 1 (Kirk-Othmer) is an encyclopedia and is given a reliability of 4 because no methods are described. The thermodynamic data are acceptable to show that boric acid has no explosion properties. Study 3 (Mak, 2004) is a statement and is considered as key study. Although no methods are described, the statement is given reliability 1 because this is the standard protocol. The statement that boric acid contains no reactive groups is acceptable to show that boric acid has no explosion properties and testing according to EC method A14 is not required. In study 2 (Rowe and Meritt, 2003) an explosion test was carried out which can be used as key study with reliability of 2. Although this study is not required for evaluation of explosive properties, this study shows that boric acid will not produce an explosion even in the form of a dust cloud. b. Experiments in the key study were carried out with batch number S013403 [redacted] Data on the purity of the active substance and on impurities are not available. c. The full reference for the key study is: [redacted] d In the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh) it was concluded that boric acid is not explosive.
Conclusion	Boric acid is not explosive

Reliability	study 1, reliability is 4 study 2, reliability is 2 study 3, reliability is 1 (key study)
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21-Feb-05
Materials and methods	Section 3.16 Oxidizing properties. a. The notifier submitted a statement (Mak, 2004) and is given reliability of 4 because no methods are described. The statement that boric acid contains no reactive groups is acceptable to show that boric acid has no oxidizing properties and testing according to EC method A17 is not required. b. In the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh) it was concluded that boric acid is not oxidising. as indicated by the notifier.
Conclusion	reliability is set at 4.
Reliability	acceptable.
Acceptability	-
Remarks	

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-Jan-08
Materials and methods	Section 3.17 Reactivity towards container material. Caution is required when storing in polypropylene at low temperatures due to brittleness of this material at low temperatures. Preferred storage material is HDPE.
Conclusion	Preferred storage material is HDPE.
Reliability	0 (not relevant).
Acceptability	acceptable.
Remarks	-

	Comments from ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1/4.2 & IIIA-IV.1 Section A4 4.1.1

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REFERENCE

Reference	BS 5688 : Part 8 :1979 ISO 1914-1972 [ISO title: Crude sodium borates for industrial use- Determination of sodium oxide and boric oxide contents- Volumetric method] (Published)
	Copyright
Data protection	No
Data owner	BSI / ISO
Criteria for data protection	No data protection claimed

MATERIALS AND METHODS

Preliminary treatment	
Enrichment	None required
Cleanup	None required
Detection	
Separation method	Not required
Detector	Chemical indicator used
Standard(s)	Standard solutions of sodium hydroxide and hydrochloric acid.
Interfering substance(s)	None identified
Linearity	
Calibration range	Not applicable for volumetric method
Number of measurements	ISO standard method

Section A4 (4.1-4.3)	Analytical Methods for Detection and Identification
Annex Point IIA4.1/4.2 & IIIA-IV.1	Section A4 4.1.1

Linearity	ISO standard method
Specifity: interfering substances	None identified
Recovery rates at different levels	Not applicable for this method
Relative standard deviation	Not applicable for this method
Limit of determination	Not applicable for this method; value will depend on standard volumetric solutions being used
Precision	
Repeatability	ISO standard method
Independent laboratory validation	ISO standard method

APPLICANT'S SUMMARY AND CONCLUSION

Materials and methods

The sodium oxide and boric oxide content are determined on the same solution. An aqueous solution is treated with excess standard hydrochloric acid solution followed by back titration with standard sodium hydroxide solution in the presence of methyl red as indicator. From this the sodium oxide can be calculated. The subsequent titration with standard sodium hydroxide in the presence of mannitol and phenolphthalein as indicator enables the boric oxide content to be calculated.

Conclusion

ISO standard method that is appropriate for industrial grades of boric acid, boric oxide and sodium borates

Of the boron-based compounds considered in the biocides dossiers, e.g., boric acid ($B(OH)_3$), boric oxide (B_2O_3), disodium tetraborates or anhydrous borax ($Na_2B_4O_7$ or $Na_2O{\cdot}2B_2O_3$), disodium octaborate tetrahydrate ($Na_2B_8O_{13}{\cdot}4H2O$ or $Na_2O{\cdot}4B_2O_3{\cdot}4H_2O$), the boron stoichiometry is uniquely described in quantifiable terms of B_2O_3 content. For example, the determination of the specific compounds above would yield B_2O_3 contents of 56.3, 100.0, 69.2, and 67.5 wt. % respectively. The boron chemistry ensures that the B_2O_3 content identifies and quantifies each pure borate compound. Similarly, the unique identification of sodium borates is revealed and confirmed when the Na_2O value is determined, and the unique ratio of the two oxides is determined. For two sodium borates listed above, this yield the distinctive ratio of 0.5 and 0.22 respectively, thereby in combination with the borate assay, uniquely identifies the compounds.

This approach is practiced worldwide and solidly based on fundamental chemistry principles. An internationally accepted procedure for boron assay from properly prepared samples is described in detail by BS 5688: Part 8 1979 ISO 2216-1972 British Standard Method for Boric acid, boric oxide, disodium tetraborates, sodium perborates and crude sodium borates for industrial use - Part 8 Determination of sodium oxide and boric oxide content of crude sodium borates. Equivalent standard borate assay methods are practiced and issued by national governments that address a host of sample types.

Properly conducted by competent analysts, the above technique will satisfy the need for an accurate determination of boron and borate compounds

1

Reliability

No

Deficiencies

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14 Sept 05
Materials and methods	a. There are no methods to determine the active substance as manufactured. The above mentioned procedure only works for pure borate compounds with known composition. A partly purified borate compound or a borate compound with other alkalimetals as counter ion (e.g. Li, K, Mg, Ca) will not be properly identified. b. The ISO method submitted was developed for the determination of sodium oxide and boric oxide in crude sodiumborates. For boric acid it is not necessary to determine the sodium oxide concentration first, because there is no sodium oxide. c. The ISO method submitted has been withdrawn on 27 May 2002 and is not supported by ISO anymore. The method has been withdrawn because the method was not verified once every 5 years. According to the notifier the Australian BS 5688 method is identical to the ISO 1914 method. According to the notifier this Australian method is still valid, but the RMS cannot verify this statement..
Conclusion	There are no methods to determine the active substance as manufactured. The ISO method submitted submitted (BS 5688: Part 8: 1979 ISO 1914 - 1972) was developed for the determination of sodium oxide and boric oxide in crude sodiumborates. For boric acid it is not necessary to determine the sodium oxide concentration first, because there is no sodium oxide. The ISO method has been withdrawn on 27 May 2002 and is not supported by ISO anymore. Because the method is still in use in Australia and the ISO method was withdrawn for the sole reason that the method was not verified anymore every 5 years, the method is considered acceptable by the RMS. -
Reliability	
Acceptability	acceptable .
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

4.2 (b) (d) Annex Point IIA 4.2	**Analytical Methods for (b) Air (d) Animal and Human body Fluids and Tissues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [x]**	
Limited exposure [ ]	**Other justification [x]**	
Detailed justification:	▪ (b) Air - Due to the lack of volatility of borates this is not a relevant compartment to measure – if necessary the analytical technique presented in A4.1 is appropriate ▪ (d) Animal and Human body Fluids and Tissues – Residues in animals mad humans are not relevant for Biocidal Uses. However, work has been carried out other purposes and due to the background levels present; the contribution from diet and the possibility of contamination of boron from sources such as glassware such measurements are technically difficult and require as specially set up laboratory.	
Undertaking of intended data submission [ ]	*Not relevant*	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	8 Feb 05
Evaluation of applicant's justification	Air: evaluated by environmental assessor Animal and human body fluids and tissues: not relevant
Conclusion	Air: evaluated by environmental assessor Animal and human body fluids and tissues: not relevant
Remarks	-
	Comments from other Member State *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA 4.2 & A4.2 (a) Soil

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INTRODUCTORY NOTE:

There are multiple methods in use for analysis of boron in soil. All the methods involve an extraction step, to remove boron from the soil matrix, and a measurement step, to quantify the extracted boron. The measurement procedures are expected to yield comparable results and typically are selected based on availability of equipment, costs, interferences and convenience. Extraction procedures are not expected to yield comparable results and typically are selected based on the question to be asked, soil properties, and agency preference.

Extraction procedures are discussed in section 3.1 below. If the objective is to measure total boron, then the soil sample can be decomposed or digested to free all forms of boron from the solid media, using strong mineral acids, heating or microwave energy, and similar procedures. These are illustrated by the US EPA Method 200.7 and the US EPA Method 3052 (Ref 3 and Ref 4 below).

If the objective is to measure bioavailable boron, then the preparation typically uses hot water or an equivalent less aggressive solvent. These are illustrated by Shuman et al and Wolf and Beegle (Ref 2 and Ref 5 below).

Analytical measurement procedures are discussed in section 3.2 below. Preparation procedures result in an aqueous solution that can then be analysed using ICP-AES (Inductively coupled plasma – atomic emission spectrometry) procedures (such as the US EPA Method 200.7, Ref 3; see also the APHA standard method described for section IIA 4.2(c)) or colorimetric procedures using azimethine-H. A standardized azimethine-H procedure is illustrated by ISO Procedure 9390 (Ref. 1).

1 REFERENCE

1.1 Reference

Ref 1: International Organization for Standardization. 1990. "ISO 9390: 1990 Water quality – Determination of borate – Spectrometric method using azomethine-H". Available online at: *http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeStandardsListPage.TechnicalCommitteeStandardsList?COMMID=3671*

Ref 2: Shuman, L.M., V.A. Bandel, S.J. Donohue, R.A. Isaac, R.M. Lippert, J.T. Sims and M.R. Tucker. 1992. "Comparison of Mehlich-1 and Mehlich-3 Extractable Soil boron with Hot-water extractable boron." Commun. Soil Sci. Plant Anal. 23 (1&2): 1-14

Ref 3: U.S. Environmental Protection Agency, Office of Science and Technology. 2001. "Method 200.7 Trace Elements in Water, Solids and Biosolids by Inductively Coupled Plasma – Atomic Emission Spectrometry." Revision 5.0 EPA-821-R-01-010. Available online at: www.lib.ucdavis.edu/govdoc/EPA/200_7.pdf

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA 4.2 & A4.2 (a) Soil

Ref 4: U.S. Environmental Protection Agency, Office of Solid Waste 1996. "Method 3052 Microwave Assisted Digestion of Siliceous and Organically Based Matrices." Available online at: www.epa.gov/SW-846/pdfs/3052.pdf

Ref 5: Wolf, A. and D. Beegle. 1995 "Chapter 5 Recommended soil tests for macronutrients: Phosphorus, Potassium, Calcium and Magnesium" in "Recommended Soil Testing Procedures for the Northeastern United States", 2nd Edition, prepared by Agricultural Experimental Stations of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont and West Virginia. Northeastern Regional Publication No. 493.Available online at: http://ag.udel.edu/extension/Informatin/Soil_Testing/title-95.htm.

Data protection

No

Data owner

Authors

Criteria for data protection

No data protection claimed

MATERIALS AND METHODS

Preliminary treatment

Enrichment

Extraction methods may be considered enrichment so are discussed in this section. Procedures are divided into methods to obtain Total Recoverable boron and to obtain Bioavailable boron.

Total Recoverable Extraction Procedures – Solid samples

Solids (soils, sediments) are extracted with either an acidic solvent with gentle heat (95°C, Method 200.7 Section 11.3, Ref 3) or with microwave energy (resulting in a higher temperature of about 180°C and pressure (Method 3052, Ref 4).

- Method 200.7, Section 11.3 (US EPA, 2001):: Sample is dried to constant volume, then ground and sieved. (To avoid contamination from borosilicate glassware, use of plastic, PTFE or quartz labware is necessary.) A representative 1.0 g aliquot is mixed with 4 mL of (1+1) nitric acid solution and 10 mL of (1+1) HCl solution. Sample is heated and refluxed for 30 minutes at 95°C, allowed to cool, then transferred to a 100 mL volumetric flask and brought to volume with reagent water. Sample is allowed to settle overnight or centrifuged. Sample also may be filtered to remove suspended solids, then analysed.

- Method 3052 (US EPA, 1996): An aliquot of 0.5 g sample is transferred to appropriate vessel, then 9 ml concentration nitric acid and 3 mL concentrated hydrofluoric acid is added to vessel. Samples with low concentrations of silicon dioxide may require less HF. Depending on matrix and co-analytes, 2 mL of concentrated hydrochloric acid and 0.1 to 2.0 mL of hydrogen peroxide (30%) may aid digestion. Reagent water may be added in small amounts (0 to 5 mL) to improve solubility and prevent temperature spikes. Vessel is sealed and placed in microwave apparatus. Temperature of sample should rise to 180 $\pm$ 5°C in approximately 5.5 minutes and remain there for a digestion time of 9.5 minutes. After cooling, sample may be allowed to settle, centrifuged, or filtered to remove suspended solids. Sample is transferred to volumetric flask and brought to volume with reagent water, then analyzed. Multiple samples may be combined to increase the total aliquot size.

Bioavailable Fraction

- Hot water-soluble boron (HWsB), (Shuman et al., 1992): 16 mL of soil were scooped and placed in a plastic boiling pouch. The pouch was weighed to determine the mass of soil. Forty mL of de-ionized water were added to the pouch along with 0.5 mL of 10% (w/v) $CaCl_2$. Each bag was sealed with heat. Bags were placed in a boiling water bath and timed for 7 min from the time the water in the bag started to boil (about 5 min after placing into the bath). Bags were removed, cooled, and cut open. Supernatant was filtered through Whatman No. 42 paper.

- Mehlich -1 (M1), (Wolf and Beegle, 1995): 5 cm^3 of sieved, air-dried soil is scooped and placed into a 150 mL extraction flask. Twenty-five mL of Mehlich 1 extracting solution (0.025 N H_2SO_4 + 0.05 N HCl) is added. The flask is shaken for 5 min on a reciprocating shaker set at a minimum of 180 oscillations per minute. Extract is filtered through a medium-porosity filter (Whatman No. 2 or equivalent). The sample can be analysed for boron, but also for P, K, Ca and Mg.

- Mehlich – 3 (M3), (Wolf and Beegle, 1995): 2.5 g or 2.5 cm^3 of air-dried, sieved soil is scooped into a 100 mL extraction bottle (plastic). Twenty-five mL of Mehlich - 3 extracting solution (0.2 N CH_3COOH + 0.25 N NH_4NO_3 + 0.015 N NH_4F + 0.013 N HNO_3 + 0.001 M EDTA) is added. The bottle is shaken at 200 oscillations per minute for 5 minutes on a reciprocating shaker. Extract is filtered through a medium-porosity filter paper (Whatman No. 2 or equivalent). The sample can be analysed for boron, but also for P, K, Ca, and Mg.

Cleanup

If colorless filtrate is needed (such as for spectrometric analysis) a small amount of activated carbon can be added during the extraction phase. If ICP is used, no carbon is needed – carbon may absorbe some boron.

Detection

Separation method

None

Detector

An appropriate analysis method may be used, such as the ISO 9390 Azimethine-H spectrometric method (Ref 1), or the US EPA Method 200.7 ICP-AES method (Ref 3). Those methods are described separately below.

The Azimethine-H procedure uses a spectrophotometer in range of 410 nm to 420 nm using a cell of optical pathlength 10 mm. Alternatively, a cell of 50 mm optical pathlength may be used to measure low boron concentrations.

The ICP-AES uses a photodetector to monitor specific wavelengths. Element specific emission spectra are produced by a radio-frequency inductively coupled plasma, dispersed by a grating spectrometer and monitored at specific wavelengths by photodetector. Multiple wavelengths are typically monitored to measure several elements. For boron, the recommended wavelength is 249.678 nm (see Table 1 of Method 200.7).

Standard(s)

Boric acid is typically used as standard. Reference solutions may be purchased from commercial suppliers

Interfering substance(s)

For the Azimethine-H method, Mn, Zr, Cr, Ti, Cu, V, Al, Be and Fe may cause high results. Fe is reported to interfere with B emission lines in ICP-AES procedure.

Linearity

Calibration range

For measures in range 0.00 to 0.20 mg/L, six standards are prepared at 0, 0.04, 0.08, 0.12, 0.16 and 0.20 mg/L (Ref 1). For measures in range 0.00 to 1.00 mg/L, standards are prepared at 0, 0.2, 0.4, 0.6, 0.8 and 1.0 mg/L (Ref 1).

Number of measurements

Ref 1 advises that six standards are measured in each range. Ref 3 advises that at least 3 non-zero standards are measured.

Linearity

For ICP-AES, a linear calibration graph is to be achieved. Ref 3 specifies that the weighted regression line achieve R^2 greater than 0.995 (Section 10.3 of Method 200.7)

For azimethine-H, a linear calibration curve is to be achieved according to Ref 1.

Analysis of field soils showed strong correlation between the HWsB and M1 or M3 extraction procedures. After extraction, samples were analysed using ICP-AES (Ref 2). HWsB is the accepted procedure, so each of the other procedures were compared to it using 620 soil samples. 300 samples were measured with the M1 extraction and 320 samples were measured with the M3 extraction. The regression equations were:

Boron (M1 extraction) = 0.089 + 0.848 * Boron (HWsB extraction), with r = 0.744.

Boron (M3 extraction) = 0.391 + 0.706 * Boron (HWsB extraction), with r=0.815

Because these samples were field samples, "true" boron concentrations were not known; however, both M3 and M1 procedures extracted more boron than the HWsB procedure (Ref 2).

Specifity: interfering substances

Mn, Zr, Cr, Ti, Cu, V, Al, Be and Fe may cause high results in the azimethine-H analysis. Ref 3 reported no interfering substances, although the B emission lines apparently suffer strong spectral interference from Fe. Use of borosilicate glass leads to contamination of samples.

Recovery rates at different levels

Recovery rate of 93.5% was reported from interlaboratory trial of 20 laboratories using standard solutions (Table 1 of ISO 9390 Method).

Relative standard deviation

Ref 1 reported reproducibility variation coefficients of the azimethine-H procedure for standard solutions- 5.9%, surface water- 5.6%, , mineral water – 3.0%, and effluent from a biological treatment plant- 3.3%. .

Limit of determination

Ref 1 reported that the azimethine-H method is applicable to determining concentrations between 0.01 mg and 1 mg of boron per liter.

Ref 2 reported detection limits of 0.0057 mg/L for ICP-AES in aqueous samples. For soil samples extracting 1 g-soil in 100 mL solution, the estimated detection limits would be 0.057 mg/L (see footnote to Table 1 in Method 200.7).

Precision

Repeatability

Ref 1 reported repeatability relative standard deviations (repeatability variation coefficients) for standard solutions - 11.4%, surface water - 12.3%, , mineral water - 7.2%, and effluent from a biological treatment plant - 6.5% (Table 1 of ISO 9390 Method).

Ref 2 reported that Method Detection Limits were 0.03 mg/L in aqueous media (Table 4 of Method 200.7). MDL for boron in solids was not reported because of glassware contamination (see footnote of Table 4).

Independent laboratory validation

Ref 1 reported that an interlaboratory trial of the azimethine-H procedure was carried out in Germany (Table 1 of Method 9390) with following reported results:

Sample	Number of laboratories	Number of Values	Outlier %	Mean value (mg/L)	ırd ɔn - bilit	Standa Deviati reprodu ty
Standard solution*	20	76	14.6%	0.234	7	0.01
Surface water	19	71	20.0%	0.151	9	0.00
Mineral water	20	75	15.7%	0.05	5	0.01
Effluent from a biological treatment plant	19	74	16.9%	1.06	9	0.03

*True value of standard was reported as 0.25 mg/L

For the ICP-AES procedure, Ref 3 reported that the ICP-AES method has been validated for boron and 30 other elements in a separate US EPA interlaboratory comparison, citing another EPA document. The citation is: US EPA, 2000. Method 6010C, "Inductively Coupled Plasma-Atomic Emission Spectrometry" Revision 3, November 2000), available online at www.epa.gov/SW-846/pdfs/6010C.pdf.

APPLICANT'S SUMMARY AND CONCLUSION

Materials and methods

The analysis of boron in soils involves an extraction to aqueous solution and analysis of that solution. The solution is analyzed using the same procedures as for an aqueous media.

Extraction with strong acids is intended to recover all trace elements, without regard to bioavailability. Such procedures are typically reported as "total" boron, or "total recoverable" boron. They are distinctly different values than would result from extractions that intend to measure the bioavailable boron, such as the HWsB, M1 and M3. For comparing boron concentrations in soil with PNEC values, the bioavailable fraction is the more appropriate measure.

Alternative analytical methods may be used following preparatory extractions from various environmental media. One preferred analytical method is ICP-AES because it permits simultaneous measurement of a large number of trace elements. The azimethine-H procedure is another method with a long record of use.

Total Recoverable Boron Extraction Methods

- Method 200.7 (Ref. 3): An aliquot of a well-mixed, homogeneous sample is accurately weighed or measured for sample processing. For total recoverable analysis of a solid or an aqueous sample containing undissolved material, analytes are solubilized by gentle refluxing with HNO_3 and HCl. For total recoverable analysis of a sludge sample containing total suspended solids $\geq$ 1% (w/v), analytes are solubilized by refluxing with HNO_3, background organic materials are oxidized with peroxide, and analytes are further solubilized by refluxing with HCl. After cooling, the sample is made up to volume, mixed and then centrifuged or allowed to settle overnight prior to analysis. For the determination of dissolved analytes in a filtered aqueous sample aliquot, or for the "direct analysis" total recoverable determination of analytes in drinking water where sample turbidity is <1 NTU, the sample is made ready for analysis by the addition of the appropriate volume of HNO_3, and then diluted to a predetermined volume and mixed before analysis.

- Method 3052 (Ref 4): The microwave digestion procedure (Method 3052) is a rapid protocol with the goal of achieving total sample decomposition. Because the method uses polymeric vessels, the procedure is especially appropriate for avoiding contamination by borosilicate glass. The use of the microwave procedure replaces the longer (and more hazardous) refluxing of a concentrated acid solution at near-boiling temperature that is part of Method 200.7.

Both these methods are performance based, that is, they focus on achieving a level of detection and accuracy, rather than requiring that every procedure be included. A laboratory is permitted to omit any step or modify any procedure provided that all performance requirements in the method are met. Consequently, the Methods include Quality Assurance/Quality Control procedures and Calibration procedures (Sections 9 and 10 of Method 200.7). These require, for example, that instrument calibration achieve an R^2 of 0.995 or better.

Bioavailable Boron Extractions Methods

Soil samples are routinely collected and analysed for bioavailable boron content. The historic standard extraction method uses hot water but several modifications have been in use. The Mehlich procedures use dilute strong acids at ambient temperature and also permit measurement of other nutrients in the same extract. In contrast, the HWsB extract is used only for boron analysis.

To compare the extraction methods, Shuman et al. (Ref 2) obtained 620 soil samples from 6 states in the southeastern US. These samples were submitted to the individual state agencies which used either the Mehlich -1 or Mehlich -3 extraction procedure. Subsamples were also analysed by the University of Georgia laboratory using the HWsB procedure. All samples were also analysed for pH, P, K, Ca, Mg and organic matter content.

The HWsB procedure incorporated some modifications from earlier versions of the procedure. For example, a sealable plastic pouch is used instead of a reflux apparatus. Calcium chloride was used to replace barium chloride and so prevent generation of a hazardous waste.

Data were subjected to correlation and regression analyses. The mean, minimum and maximum data are given in the table below.

HWsB Extraction (mg-B/dm3)

State	*Mean*	*Min*	*Max*
Delaware	0.40	0	0.02
Maryland	0.22	0	0.79
N. Carolina	0.23	0	0.78
Virginia	0.34	0	1.53
S. Carolina	0.40	0.13	0.01
Georgia	0.21	0	0.76

Mehlich Extraction (mg-B/dm3)

	Mean	*Min*	*Max*	*Type*
Delaware	0.66	0.22	1.90	M-3
Maryland	0.62	0.28	1.47	M-3
N. Carolina	0.50	0.19	1.14	M-3
Virginia	0.43	0.13	2.13	M-1
S. Carolina	0.39	0.10	1.22	M-1
Georgia	0.26	0.05	0.93	M-1

Relative Extraction (Mehlich/HWsB)

	Ratio of Means	*Type*
Delaware	165%	M-3
Maryland	282%	M-3
N. Carolina	217%	M-3
Virginia	126%	M-1
S. Carolina	98%	M-1
Georgia	124%	M-1

The results show that the Mehlich procedures consistently extracted more boron than the HWsB procedure, and that the M3 appeared to extract more than the M1 procedure, although the soils were different.

Correlations between HWsB and weight per soil volume were negative, i.e., the coarser, less dense soils had less boron capacity than the finer grained soils. The correlations between HWsB and M1 show considerable scatter at low B values, but the authors conclude that values above 0.5 mg/dm^3 show a good correlation (overall correlation of r=0.744). The correlation between HWsB and M3 show less scatter than the M1 comparisons, and a slightly larger correlation (r=0.815).

The studies used a standard soil volume, following the widespread practice of soil testing laboratories, and the authors point out the inaccuracies that result from assuming a constant bulk density.

Analysis of Boron using Azomethine-H

The principle of the analysis (Ref 1) is the reaction of dissolved forms of borate with Azomethine-H, which is the condensation product of H-acid (8-amino-naphth-1-ol-3,6-disulfonic acid) and salicylaldehyde. A yellow complex is formed at a pH of about 6, which is measured spectrometrically at the absorption maximum in the range of 410 to420 nm. A cell with longer optical path length (50 mm) can be used for measurements in the range 0.0 to 0.2 mg of boron per liter, while a cell of shorter path length (10 mm) can be used for concentrations up to about 1.0 mg of boron per liter. The working range may be extended by dilution.

Analysis of Boron using ICP-AES

The analysis described in Method 200.7 (Ref 4) involves multi-elemental determinations by ICP-AES using sequential or simultaneous instruments. The instruments measure characteristic atomic-line emission spectra by optical spectrometry. Samples are nebulized and the resulting aerosols are transported to the plasma torch. Element specific emission spectra are produced by a radio-frequency inductively coupled plasma. The spectra are dispersed by a grating spectrometer, and the intensities of the line spectra are monitored at specific wavelengths by a photosensitive device. Photocurrents from the photosensitive device are processed and controlled by a computer system. A background correction technique is required to compensate for variable background contribution to the determination of the analytes. The background must be measured adjacent to an analyte wavelength during analysis. Interferences must be considered and addressed appropriately.

The US EPA states that this method has been validated for boron and numerous other trace elements. EPA has included the ICP-AES procedure among its testing procedures for solid waste; the current protocol is "Method 6010C Inductively Coupled Plasma-Atomic Emission Spectrometry" (available online at www.epa.gov/SW-846/pdfs/6010C.pdf, Revision 3, dated November 2000). Method 200.7 is a consolidation of methods for water, wastewater and solid wastes – including soil – so incorporates much of the Method 6010C text. Consequently, Method 6010C is not reviewed separately.

Conclusion

Validity criteria are met.

The field extraction studies (Ref 3) show significant correlations between extractable boron obtained using the HWsB procedure, considered the most widely used procedure for estimating bioavailable boron, and two Mehlich procedures that use strong acid extraction. The authors conclude that the Mehlich procedures can be used as substitutes for the HWsB procedure. The Mehlich extracts can be analysed for other nutrients, resulting in improved laboratory efficiency.

The comparative extraction study also illustrates that there is no single extraction procedure that is universally accepted for estimation of bioavailable boron. The lack of strong correlation with other soil properties also suggests that the bioavailable boron fraction is not simply determined by soil properties such as pH or organic matter content.

The Azomethine-H procedure is accepted by the International Organization for Standardization as applicable in the determination of borate in concentrations between 0.01 mg and 1 mg of boron per liter.

The ICP-AES procedure is accepted by US EPA as a validated procedure for water, wastewater and solid wastes – including soil. The acid extraction methods described are also accepted US EPA Methods for measurement of total boron. Depending on extraction procedures, detection limits are estimated to be in the range of 5.7 µg/L or 57 µg/kg.

Reliability

1- reliable without restriction

Deficiencies

No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25-04-2005
Materials and methods	Applicant's version is acceptable with the following additions: azimethine-H should read azomethine-H EPA method 6010C "Inductively Coupled Plasma-Atomic Emission Spectrometry" gives an estimated instrumental detection limit (IDL) for boron of 3.8 µg/L. This IDL should be considered illustrative. With a soil:solution ratio during extraction of ca. 1:15 (reflux) or 1:30 (microwave), the detection limit would be equivalent to 60 - 120 µg/kg. The interlaboratory validation reported in EPA 6010C did not include boron, method 200.7 (INDUCTIVELY COUPLED PLASMA—ATOMIC EMISSION SPECTROMETRIC METHOD FOR TRACE ELEMENT ANALYSIS OF WATER AND WASTES - METHOD 200.7) does contain a validation report.
Conclusion	Depending on the research question, different extraction methods can be used to differentiate between the total boron fraction and the fraction that is assumed to be more related to the bioavailable part. Total boron can be extracted from soil by hot acid extraction with HNO_3 and HCl under reflux or by microwave digestion with HNO_3 and HF. Several extraction methods are used to estimate the bioavailable boron fraction, of which the hot water soluble extraction is the most widely used. Detection can be done by spectrophotometry (reported detection limits between 0.01 - 1 mg B/L) or ICP-AES (detection limit ca. 4 µg/L). Assuming a soil:acid ratio during extraction of 1:15 (reflux) or 1:30 (microwave), corresponding detection limits in soil are 0.15 – 0.30 mg B/kg with the azomethine-H method or 60 - 120 µg/kg soil using ICP-AES. In general, it can be stated detection by ICP-AES is preferred, since this is a direct method and no intermediate reaction is needed. Furthermore, the detection limits for ICP-AES are lower. .
Reliability	1
Acceptability	acceptable
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA 4.2 A4.2 (c) Water

Official use only

REFERENCE

Reference

Standard Methods for the Examination of Water and Wastewater. Seventeenth Edition. Prepared and published jointly by; American Public Health Association, American Water Works Association, Water Pollution Control Federation

Electronic File

Data protection

No

Data owner

Criteria for data protection

No data protection claimed

MATERIALS AND METHODS

Preliminary treatment

Non-entry field

Enrichment

None

Cleanup

Filtration to remove particulates

Detection

Non-entry field

Separation method

Not required

Detector

Inductively coupled plasma emission spectroscopy using either a monochomator or polychromator depending on instrument used

Standard(s)

External standard using boric acid

Interfering substance(s)

Linearity

Non-entry field

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA 4.2 A4.2 (c) Water

Calibration range	APHA method suggests 1.0 – 50 mg B/l
Number of measurements	No data provided in this standard method
Linearity	No data provided in this standard method
Specifity: interfering substances	Normally not present in water samples. Matrix matched standards minimise interference as does choice of spectral line
Recovery rates at different levels	
Relative standard deviation	No data provided in this standard method
Limit of determination	APHA method suggests 5µg B/l
Precision	Non-entry field
Repeatability	The following information is given in APHA methods for boron in concentration range 19 – 5189 µg B/l (total digestion) X = 0.8807 C + 9.0 S = 0.1150X + 14.1 SR = 0.0742 X + 23.2 where X = mean recovery, µg/l C = true value, µg/l S = multi-laboratory standard deviation, µg/l SR = single analyst standard deviation, µg/l
Independent laboratory validation	No data provided in this standard method

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA 4.2 A4.2 (c) Water

APPLICANT'S SUMMARY AND CONCLUSION

Materials and methods

Samples collected and stored in polyethylene bottles or alkali-resistant, boron-free glassware. Particulates should be removed through a 0.45 micron filter. Samples are aspirated though a nebuliser into an inductively coupled plasma spectrometer (ICP) and the boron emission is measured at the 249.77 nm wavelength to minimise spectral interferences. Standard boron solutions (made from boric acid) covering the expected analytical range are also aspirated and used as a calibration curve. Reagent blanks also need to be run. Method essentially measures boron. This can be converted to the active substance by multiplying by the appropriate conversion factor assuming that no other boron containing substances are present.

Conclusion

The ICP method for boron analysis has become the standard technique for this determination in water as it has a good dynamic working range minimal interferences, no extraction or concentration required to achieve required detection limits and is quick.

This technique can be used for the determination of boron in other matrices provided that they can be extracted into an aqueous phase. Recovery rates, spectral and molecular interference as well as physical factors(e.g viscosity compared to standards) have to be carried out

ICP methodology is cited in various standard procedures such as

EPA-NERL method number 200.7

EPA-OSW method number 6010 C

ASTM method number D 1976

1

Reliability

No

Deficiencies